Data Management, data solutions and associated services specification

1. Executive summary

The Healthcare Quality Improvement Partnership (HQIP) is seeking to procure the following services for the National Joint Registry (NJR).

- NJR data management, solutions and (optional) associated services

HQIP is not only looking for organisations to provide these services but also to partner with organisations that can demonstrate the following characteristics:

- Strategic and solution orientated
- Proactive, responsive and flexible
- Ability to add value
- Committed to continual improvement
- Communicative and effective team player
- Innovative

The NJR currently comprises two core service areas, one of which is the Contract stated above. The second is a NJR statistical analysis, support and associated services contract.

The purpose of this document is to provide potential suppliers with information covering the full range of core services required for NJR data management and data solutions. The document also provides information on a set of optional associated services.

The associated services are a set of general administrative requirements. These are optional services that relate to the delivery of other elements of the NJR data management and solutions service and may or may not be included in the final Contract.

2. Overview

2.1. Background and brief introduction to the NJR

2.1.1. History

Joint replacements have become common and highly successful operations that bring many patients improved mobility and relief from pain. Thousands of such operations take place in the UK every year.

A wide range of implants can be used in joint replacement operations and the NJR helps to monitor the performance of these implants and the effectiveness of different types of surgery; improving clinical standards and benefiting patients, clinicians and the orthopaedic industry.

The NJR was set up in April 2002 by the Department of Health (DH) and Welsh Government following a National Audit Office report into a failing ‘3M’ hip implant. From 1 April 2008, hosting arrangements for the NJR were transferred from the DH to HQIP.

The NJR has collected hip and knee replacement data since April 2003, ankle replacement data since April 2010 and data for elbow and shoulder replacements since April 2012.

The NJR also extended to Northern Ireland in February 2013, the Isle of Man in July 2015 and the States of Guernsey in November 2019.

The DH provided the initial start-up funding for the NJR. However, the system is now self-financing through a subscription charge on each 'eligible' hip, knee, ankle, elbow and shoulder implant which is payable by NHS Trusts (England), Health and Social Care Trusts (Northern Ireland), Local Health Boards (Wales) and independent (private) healthcare providers. The cost to the NHS was reduced in 2014 through a contributory financial subscription arrangement with the orthopaedic device industry whereby an annual subscription is charged for provision of the NJR Supplier Feedback service and other bespoke reporting.

Since April 2014, the NJR subscription has been invoiced annually and the income managed in a dedicated fund at HQIP, governed by the NJR Steering Committee (NJRSC). Prior to this, the registry operated a levy system.

2.1.2. NJR mission statement

The purpose of the National Joint Registry, which covers England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey, is to collect high quality and relevant data about joint replacement surgery in order to provide an early warning of issues relating to patient safety. In a continuous drive to improve the quality of outcomes and ensure the quality and cost-effectiveness of joint replacement surgery, the NJR will monitor and report on outcomes, and support and enable related research.

2.1.3. NJR Strategic objectives

The NJR's strategic goals are to:

- Monitor in real time the outcomes achieved by brand of prosthesis, hospital and surgeon, and highlight where these fall below an expected performance in order to allow prompt investigation and to support follow-up action.
- Inform patients, clinicians, providers and commissioners of healthcare, regulators and implant suppliers of the outcomes achieved in joint replacement surgery.
- Evidence variations in outcome achieved across surgical practice in order to inform best practice.
- Enhance patient awareness of joint replacement outcomes to better inform patient choice and patients' quality of experience through engagement.
- Support evidence-based purchasing of joint replacement implants for healthcare providers to support quality and cost effectiveness.
- Support suppliers in the routine post-market surveillance of implants and provide information to clinicians, patients, hospital management and the regulatory authorities.

2.1.4. NJR Strategic Plan and Annual Work Plan

The NJR Strategic Plan is a living document (currently dated 2018-21) and subject to ongoing review and amendment in line with changing business priorities and changes in the wider external environment. A new strategic plan will be developed in 2021.

To assist in the delivery of this Strategic Plan, an annual work plan is developed each year in order to set specific objectives and associated Key Performance Indicators (KPIs) to be achieved against each work programme.

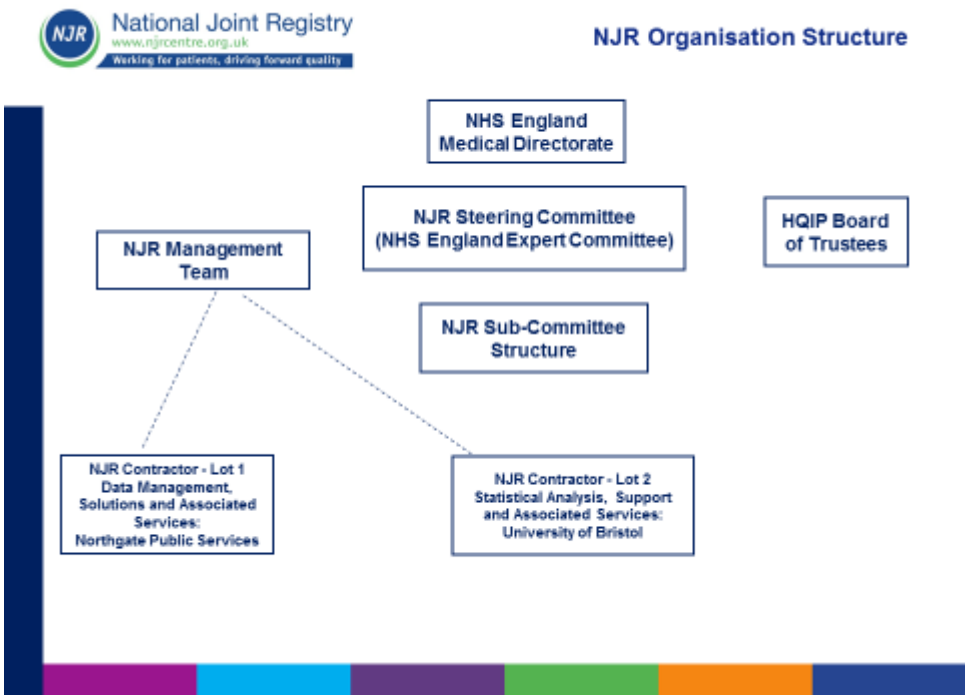
The Strategic Plan and Annual Work Plan are agreed and owned by the NJRSC.

Progress against the Annual Work Plan is monitored by the NJR Executive Committee (NJREC). Progress, along with associated project plans and budget considerations, is reported to the NJRSC quarterly.

Further detail is also shared annually in the public domain as part of the NJR's Annual Report (www.njrreports.org.uk).

2.2. Role definitions

This section defines the various roles of the parties involved in the running and direction of the NJR.



2.2.1. Healthcare Quality Improvement Partnership

HQIP, a charity and company limited by guarantee, is an independent organisation, which works in partnership with patients and healthcare professionals to influence and improve healthcare practice at all levels. It is led by a consortium comprising the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. HQIP commissions, manages, supports and promotes national and local programmes of quality improvement. This includes the National and Local clinical audit programmes and the Clinical Outcome Review Programmes.

The NJR is not a legal entity as established, so consequently it requires a host. HQIP provides that role and 'hosts' the NJR Management Team (NJRMT) acting as authority for NJR Contracts as well as assuming data controller responsibility (jointly with NHS England) and is responsible for NJR's compliance with the necessary legal and statutory frameworks;

The Contractor for the NJR data management, solutions and associated services is a data processor alongside the NJR statistical analysis, support and associated services Contractor. Both Contractors process personal data, but only the former processes patient identifiable data.

HQIP oversees all data sharing agreements with NJR stakeholders and peer and partner organisations including collaborations, for example, with Getting It Right First Time and Beyond Compliance.

2.2.2. National Joint Registry Steering Committee (NJRSC)

The NJRSC was established in 2002 to oversee the strategic development and running of the NJR programme. It sets the strategic direction of the NJR, with the NJRMT managing the work programme approved by the NJRSC and sub-committees. The NJRSC is an NHS England Committee of Experts and meets quarterly.

The NJRSC is responsible for the overall NJR budget and approval of work, supported by appropriate business cases, aligned to the NJR Strategic Plan. The NJREC hold delegated authority for budget approval or adjustment where appropriate.

HQIP manage the NJR funds on behalf of the NJRSC. The NJR's financial position is included in the audited accounts of HQIP.

The full audited accounts are available on the HQIP website (www.hqip.org.uk), and also from the Charity Commission and Companies House.

NJRSC membership currently comprises:

- 1 Chair
- 1 NJR Medical Director / Vice Chair
- 3 Orthopaedic surgical profession representatives
- 1 Public health and epidemiology representative
- 2 Orthopaedic implant supplier representatives
- 1 Practitioner with special interest in orthopaedics
- 2 Patient representatives
- 1 NHS Trust management representative
- 1 Independent healthcare sector representative

Co-opted members include:

- Chair of the NJR Regional Clinical Coordinators Committee
- National Director for Clinical Improvement for NHS England/Improvement
- Representative of the Medicines and Healthcare products Regulatory Agency
- Representative of the Welsh Government
- A specialist in healthcare sector procurement
- President of the British Orthopaedic Association

Attendees include representatives of:

- The NJR Management team
- Healthcare Quality Improvement Partnership

- NJR Contractors

The NJRSC membership and declarations of interest can be found online and are included annually as part of the NJR Annual Report.

2.2.3. NJR Sub-committees

2.2.3.1. Committee structure function and purpose

- Provides effective management, coordination and monitoring of complex NJR work streams
- Provides a transparent approach for management of NJR business agendas, minutes and action plans
- Provides effective clinical leadership and stakeholder involvement in NJR work

Currently, there are eight NJR sub-Committees and each is chaired by a NJRSC member to direct and co-ordinate specific areas of work within the NJR. These meet on a regular basis, either remotely or at a London location:

2.2.3.2. Executive Committee (NJREC)

Key role: The NJREC is responsible to the NJRSC for ensuring the effective operational and financial management of the NJR, by providing strategic support and decision-making on an ongoing basis. It has delegated authority from the NJRSC. The NJREC currently meets quarterly.

2.2.3.3. Medical Advisory Committee (MAC)

Key role: The MAC provides clinical engagement and advice on the development of NJR-wide programmes of work including representation from relevant orthopaedic specialist societies. The MAC currently meets three times per year.

2.2.3.4. Implant Scrutiny Committee (ISC)

Key role: The ISC is responsible for the development and management of the implant outlier process and monitoring of orthopaedic device performance, reporting to the Medicines and Healthcare Products Regulatory Agency where necessary. The ISC currently meets quarterly.

2.2.3.5. Surgical Performance Committee (SPC)

Key role: The SPC is responsible for the development and management of the surgeon and hospital outlier process and monitoring surgeon and unit performance. The SPC currently meets quarterly.

2.2.3.6. Research Committee (RC)

Key role: The RC is responsible for the development of the NJR research strategy and management of the research function including the review and approval of research and NJR data access requests. The RC currently meets quarterly.

2.2.3.7. Editorial Board

Key role: The Editorial Board is responsible for the management of the production and development of the NJR Annual Report. The Editorial Board currently meets five to six times per year

2.2.3.8. Regional Clinical Coordinators' (RCC) Committee

Key role: The RCC Committee is a committee of consultant orthopaedic surgeons who, as designated NJR Regional Clinical Coordinators, act as local champions to support the work of the NJRSC, other sub-committees and the NJR Compliance Officers. The RCC Committee currently meets three times a year.

2.2.3.9. Data Quality Committee (DQC)

Key role: The DQC is responsible for the development and management of the current NJR Data Quality Strategy and its implementation; including oversight of the NJR data quality audit programme. The DQC currently meets quarterly.

2.2.4. Working Groups

In addition, a number of project-specific working groups operate to oversee elements of the NJR work programme in support of the committees, or convened on an ad-hoc basis to manage specific areas of NJR work. Groups can be disbanded when work is considered to have been concluded and/or new groups convened as necessary. Current working groups include:

- NJR PROMS Working Group
- NJR Minimum Dataset Working Group
- NJR Component Database Working Group
- NJR Shoulder and Elbow Working Group
- NJR Implant Methodology Working Group

2.2.5. The NJR Management Team (NJRMT)

The NJRMT, led by the NJR Director of Operations, oversee the day-to-day operational management and development of the NJR's programme of work and support the NJRSC in providing governance and strategic oversight of the NJR. The NJRMT also manages the performance and delivery of this Data management, solutions and associated services and other NJR contracts (as outlined in section 2.2.6).

Reporting lines to HQIP as the Authority will be to the NJRMT unless specified otherwise.

2.2.6. Current NJR support contracts

NJR Contractor Lot 1
Responsible for:

- Data Collection
- Data Management and Solutions and Associated Services
- Management of IT Systems and Electronic Feedback systems

NJR Contractor Lot 2
Responsible for:

- Statistical Analysis
- Statistical Support and Advice
- Enabling and promoting Research

3. Data Management, Solutions and (Optional) Associated Services – Summary

3.1. Business need and vision

The NJR is the largest orthopaedic device registry in the world with over 3 million records. The NJR's work in collecting and monitoring information on joint replacement operations is vital to improve clinical standards and benefit patients, clinicians, hospitals and the orthopaedic sector as a whole.

- The NJR's mission is to help ensure that patients receive the best clinical care before, during and following their joint replacement surgery. The NJR will continue to assist patients considering joint replacement to make evidence-based choices about their treatment and share decision-making with their clinicians when considering the benefits and risks of undergoing joint replacement.
- The NJR has been cited as a 'global exemplar' of an implantable medical devices registry in the Cumberlege report based on its clinically led model, quality of data and reporting, and cutting-edge developments. The NJR is supportive of a national strategy to reproduce the NJR model in the wider health sector and share best practice
- The NJR will continue to develop its systems in line with changing and developing needs of patients, changes in clinical practice and within the orthopaedic industry, to remain at the cutting edge of the safety and improvement agendas.
- The NJR aims to continue developing cutting-edge enhancements to its data collection, database and reporting systems for use by its many stakeholders. Key to its strategy is the ongoing, continuous alignment with developing clinical practice as well as the ability to acquire data extracts other sources that can be analysed and reported on.
- The NJR requires system and processes that provide an inherent flexibility for future changes; that enhance public and user interrogation of the data and have the capacity to extend and upscale to support additional audits and registries and to allow interoperability across different platforms.
- The NJR will be open to changes that require it to expand its footprint of current data collection against the backdrop of Cumberlege with the potential to look beyond current implant groups to relevant, related areas
- The NJR will engage and work collaboratively with other registries and databases as well as patients, providers of healthcare services across the NHS and independent sectors, commissioners, policymakers and the orthopaedic manufacturing industry.
- Data quality, accuracy and completeness is at the heart of NJRs service and work will continue to develop new methods to investigate data quality and ensure missing data is identified and captured.
- With an eye to anticipating future, and as yet unknown, requirements, it is critical that the NJR is able to draw upon expertise to utilise and develop novel methods of analysis and robust methodologies to address future work that will arise but which is not yet possible to anticipate.

To achieve this vision, the NJR requires a fully managed service for capturing and managing information about hip, knee, ankle, elbow and shoulder joint procedures carried out in England, Wales, Northern Ireland, the Isle of Man and the States of Guernsey for both public and independent sector healthcare providers.

The following service outcomes are essential to the NJR in terms of how it contributes to performance, health service outcomes and patient safety at an organisational and wider NHS and health care sector level

Key elements include but are not limited to:

- Collection and management of procedure data through direct input via a secure web-portal
- Collection of and management of procedure data through interfaces with in-situ patient systems
- Secure storage of procedure data
- Secure storage of other NJR captured data
- Validation systems to ensure that all data entered is credible
- Validation and management systems to ensure data quality, retrospectively and prospectively
- Reconciliation, linkage and comparison of data with key national datasets including Hospital Episode Statistics (HES), Patient Episode Data for Wales (PEDW), national and NJR-delivered Patient Reported Outcome Measures (PROMs) and Orthopaedic Data Evaluation Panel (ODEP) ratings
- Reconciliation, linkage and comparison of data with other national and international datasets
- Development and management of an appropriate continuous monitoring system
- Production and publication of standardised datasets and reports including potential outlier identification, ad hoc data requests, research requests and patient operation data requests
- Production of the NJR Annual Report datasets and related linked datasets
- Regional stakeholder user support to promote data quality and a helpdesk and notification service for all NJR data management and data solutions activities
- Training of end-users for all NJR data management and data solutions activities
- Supporting formal data collection, patient consent and other information governance applications to regulatory and responsible agencies as and when required
- Advice and expertise as appropriate to the role in regards to national and international best practice in registry development
- Delivery of a fully managed data solutions service to support and increase accessibility and use of data by NJR stakeholders. This includes the hosting, maintenance, management, development and data processing associated with stakeholder information services available on, at or through www.njrcentre.org.uk.

Optional associated services

- Routine collection of Patient-Reported Outcome Measures (PROMs) at a number of follow up points for the duration of the contract
- Routine collection of Patient-Reported Experience Measures (PREMs)
- NJR Annual Report project management support
- Expenses administration support to NJRSC and NJR sub-committees

3.2. Value for money

- The NJR is funded through a mandatory subscription charge which helps the NJR to provide many beneficial services to its users and funds delivery of the NJR's strategic work programme and running costs. Details of the benefits, which the NJR provides to Trusts and hospitals can be found by clicking on the following link.
- As much of NJR's subscription income is from public funds from NHS hospitals, or the performance of NHS surgery and independent sector units, the NJR is subject to scrutiny and

must demonstrate value for money and meet affordability criteria. Every year, NJR subscription charges are reviewed and set by the NJRSC, which is overseen by NHS England/Improvement (NHSEI) with the aim of ensuring cost effectiveness and value for money. This approach is also reflected in the way that NJR procures its data collection and analysis services from its suppliers.

- The size and value of orthopaedic healthcare offers the potential to provide huge patient safety and cost saving benefits to the NHS and wider health service. Potential suppliers must indicate how they would contribute and demonstrate a significant return on investment both to the NJR and the wider health sector through value added services, potential cost savings and demonstrable cost effectiveness models. In addition they will also be called upon to outline how they intend to minimise costs associated with the delivery of the service.

4. Scope of the contract

4.1. Current service arrangements

4.1.1. How the NJR is run

The governance and management set up of the current service provision is outlined in section 2.2.

- The NJR is hosted by HQIP and overseen by a Steering Committee (NJRSC), which is designated as an NHS England (NHSE) Expert Committee. The NJRSC Chairman reports directly to the NHSE Medical Director.
- NJR core services are managed under two Contracts: Lot 1 for collection and management of data and technology and Lot 2 for provision of statistical support and analysis of data, to support NJR outcome monitoring, research activity and publications.
- The NJRMT is responsible for the overall operational and contract management of the NJR and for supporting the work of the NJRSC and its sub-committees.
- We aim to have patient representatives on all of our committees, ensuring patient considerations are embedded across our work and activities.
- The services provided by the NJR are used extensively by patients, clinicians, hospital management staff, implant manufacturers/the orthopaedic industry and regulatory bodies such as the CQC and MHRA. The data is also used by commissioners of health services and national bodies such as GIRFT and Beyond Compliance.
- NJR works collaboratively with a number of key stakeholders undertaking extensive stakeholder engagement. The stakeholders have defined roles and responsibilities and service delivery is under agreed Memoranda of Understanding and Data Sharing Agreements
- Operation and patient information in the NJR is used to link to other healthcare information, including data held by NHS Digital and Digital Health and Care Wales.

4.1.2. Current activity and volumes of the service

- **Table 1 – Volume of procedures**

	March 2020-April 2021	March 2016 – April 2021
No. of NHS Trusts contributing to NJR	143	143
No. of independent treatment centres/units contributing to NJR	177	186
Total no. of units contributing to NJR	424	444
Total no. of hip procedures entered on NJR in period	56,828	521,813
Total no. of knee procedures entered on NJR in period	50,725	537,333
Total no. of ankle Procedures entered on NJR in period	520	4,728
Total no. of elbow procedures entered on NJR in period	687	4,717
Total no. of shoulders procedures entered on NJR in period	3,902	38,362
Total procedures entered on NJR in period	112,662	1, 106,953
All NJR related procedures that took place in period as entered on HES/PEDW*	Not yet available	596,363
Patient consent rate (%)	90.70%	94.50%
Valid patient national identifier (%)	95.20%	97.50%
% procedures entered into NJR with patient consent and NHS number	68.10%	79.00%

****HES/PEDW data include England and Wales's data only (excl. Isle of Man, Northern Ireland, States of Guernsey and the Independent sector)***

Table 2: System user volumes

System Name	No. of Users	Recorded Usage March 2020-April 2021	Recorded usage March 2016 – April 2021	Access type (restricted/public facing)
Data entry	Approx. 8,600	82,172	125,825	Restricted
Clinician Feedback	Approx. 4,000	14,398	19,969	Restricted
Management Feedback	402	160	308	Restricted
Component Database	270	160	304	Restricted
Data Access Portal	35			Restricted
Supplier Feedback	270	1036	1251	Restricted
Flight Deck	30			
Outlier Management System	8	103	64	Restricted
NJR Centre	All internet	96,972	114,472	Public facing
Online Annual Report	All internet	25,013	34,819	Public facing
Surgeon Hospital Profile	All internet	97,050	167,232	Public facing

4.2. Description of service

The scope of service to be delivered is for the Contractor to maintain and develop the NJR data management, data solutions and associated services function on behalf of the NJR and under the strategic direction of the NJRSC, and deliver the aims and business vision and objectives of the NJR. The scope includes

- Collection and management of procedure data through direct input and interface systems
- Secure storage of procedure data and other NJR captured data
- Validation and management systems to ensure data quality and credibility
- Reconciliation, linkage and comparison of data with key national and international datasets
- Development and management of an appropriate continuous monitoring system
- Production and publication of standardised datasets and reports including potential outlier identification, ad hoc data requests, research requests and patient operation data requests
- Production of the NJR Annual Report datasets and related linked datasets

- Delivery of support services to include a helpdesk and notification service, maintenance of contacts database and end-user training and tools
- Support for formal data collection, patient consent and other information governance applications to regulatory and responsible agencies as and when required
- Advice and expertise as appropriate to the role in regards to national and international best practice in registry development
- Delivery of a fully managed data solutions service to support and increase accessibility and use of data by NJR stakeholders. This includes the hosting, maintenance, management, development and data processing associated with stakeholder information services available on, at or through www.njrcentre.org.uk.

4.3. Immediate strategic priorities of the service

- Augmentation of the current potential outlier performance reporting to include shoulder, elbow, and ankle outcomes (subject to data quality)
- Development, review and update of the minimum dataset and implementation in associated data collection and reporting systems
- Improvement of the quality of datasets through data management and data cleaning processes
- Implementation of processes to deliver a consistent, common analysis dataset to be used for outputs across all NJR functions

4.4. Interdependencies with other services

The Contractor is expected to work very closely with the NJR statistical analysis, solutions and associated services Contractor who have the responsibility for data analysis and reporting based on the datasets that the Contractor provides. The Contractor will be required to maintain an ongoing collaborative and professional working relationship with the NJR statistical analysis, solutions, solutions and associated services contractor to agree data cleaning and format, resolve issues of data quality and work on relevant NJR development activities.

5. Detailed Requirements

5.1. Background

5.1.1. Service specification summary

The NJR data management services and associated services are known collectively as the NJR Centre. The Contract is for the provision of a fully managed service for capturing and managing information about hip, knee, ankle, elbow and shoulder joint procedures carried out in the UK for both public and independent sector healthcare providers. Key elements include, but are not limited to, data collection and management of information relating to orthopaedic surgical procedures including additional revisions and non-revisions performed on joint replacements, dataset production, information for patients, surgeons, units and manufacturers, and optional associated services.

5.2. Scope of the contract

5.2.1. Data collection and management

5.2.1.1. Data collection

- The Contractor is expected to provide a platform capable of delivering the entire data management service or to make appropriate arrangements with any third party. This platform (including any linked systems) should be in line with guidance published here by NHS Digital.
- The platform will allow collection and management of procedure data through direct input via a secure web-portal accessed via NJR Connect Data Services
- Data capture mechanisms must be flexible to change, upscale or downscale to interface with third party national data collections as wider healthcare device registry systems are implemented.
- In the delivery of the Contract, collection and management of procedure data should be permitted by developing interfaces with in situ patient information systems in hospitals
- Continual improvement of the web-portal interface to adhere to user requirements and as determined by the NJRSC must be undertaken across the duration of the contract

5.2.1.1.1. Data entry portal

- The NJR data entry system is the means by which data is captured. Procedure data is generally entered by a suitably authorised person in each participating unit (NHS hospitals and/or independent healthcare providers in England, Wales and Northern Ireland, the Isle of Man and Guernsey). This may potentially include other territories in the future.
- This data may be entered by units by means of a web-portal
- Security of the NJR data entry system must comply with both BS7799/ISO IEC 17799 IPU and all current NHS standards. Also where relevant definitions exist, data (and the security and use thereof) shall continue to comply with the relevant parts of the NHS Data Dictionary
- The Contractor is responsible for the continual improvement of the web-portal interface and the Contractor should factor this into their costings as part of the core service.
- The Contractor is required to deliver an interface that is mobile ready and that adheres closely to user requirements (visual and functional) and best practice and overall corporate branding. The Contractor is required to do this in collaboration with the NJRMT.

Key outputs:

- An annual plan to outline intended web-portal user interface improvements and enhancements.

5.2.1.2. Dataset review and update

- The set of data fields collected by the NJR is known as the Minimum Data Set (MDS). The majority of MDS data fields relate to the patient's operation details and are collected in the operating theatre. The current dataset is available here
- As of the April 2021, the NJR database held date on over 3.1 million cases submitted by NHS and independent (private) healthcare providers in England, Wales, Northern Ireland, Isle of Man and States of Guernsey.
- The current NJR MDS (version 7) was introduced in June 2018. Current datasets are reviewed every 3-5 years. Maintaining the clinical relevance of the NJR datasets is important

and further development of the MDS will be required over the course of the contract period. It is anticipated that this development would be undertaken by the contractor following consultation as directed by the NJRMT.

- The Contractor will be required to carry out further development and updates to the component database early in year 1 of the contract (version 8) and year 4/5 of the contract (version 9).
- The Contractor will be required to carry out an interim review and an update to the MDS in year 2/3 (version 8.5) of the contract to update datasets relating to elbow and ankle surgery.
- The contractor will be required to introduce minor dataset changes on an annual basis as required by the NJRMT.
- Development and review may include widening to include capture of data on additional joints. Delivery of changes to data collection systems and any related reporting systems will be required.
- Update and deployment of MDS (version 8) and subsequent versions to be executed via the platform architecture.
- All communications to stakeholders and units concerning MDS changes will be undertaken by the NJRMT
- MDS changes will be discussed and agreed under the leadership umbrella of the NJR MDS Working Group and NJRMT. The contractor will document the final list of approved changes once agreed and confirmed by the working group and NJRMT
- The Contractor will, through its Compliance Officers (staff charged with overseeing regional hospital support, see section 5.2.4.3) work nationally with units to ensure that all procedure data is accurately entered onto the NJR within at least 1 month (30 days) of the procedure date.

5.2.1.3. Bulk upload

- Units may also elect to enter the data using their existing patient administration systems (PAS), Electronic Patient Record (EPR) and theatre systems, to diminish their administrative burden and to avoid duplication of data entry.
- The exchange of data should be encrypted (SSL) where it leaves organisational boundaries. The Contractor is required to publish the interface standards for this upload so that third party suppliers of hospital systems can amend their applications to support the interface
- The Contractor is also required to manage appropriately the permission for use of the interface.
- The units inputting their data will use their own IT equipment and a barcode reader.
- The bulk upload facility is currently used by 13 units and captures hip and knee primary and revision procedures only. The Contractor is required to monitor the need for a bulk upload facility for shoulder procedures and may be required to develop the system over the course of the contract period for these and other joints as directed by the NJRMT. The Contractor should factor this into their costings as part of the core service

Service level requirements:

The supplier must ensure that both the web interface and bulk upload facility meet the following service levels, it should be noted that this is not an exhaustive list:

- System accessible for 99% of the time; i.e. 24 hours a day, 365 days per year
- System must be compatible with all current accessibility standards, major browsers (MS Edge, Mozilla Firefox, Safari and Google Chrome) and must support both the current version and the previous major versions (and all minor releases between versions).

Key outputs:

For both the web portal and the bulk data upload facility the following reports shall be provided on a monthly basis

- Report detailing system availability as a percentage; System availability is calculated by dividing uptime by the total sum of uptime and downtime.
- Report detailing usage by:
    - hour of day
    - day of week
    - day of month
    - type of procedure
    - by unit
    - by region.

5.2.1.4. PROMs/PREMs

- The Contractor will provide details of an optional service (see Optional Associated Services section 5.5) to facilitate :
- The Contractor will deliver routine linked capture using a combination of postal and electronic questionnaires, of pre and post-operative Patient Reported Outcome Measures (PROMs) data for hip, knee, and shoulder procedures up to 1, 3 and 5 years after implantation. Collection will be within timescales agreed by the NJR.
- The Contractor will deliver routine linked capture of Patient Reported Experience Measures (PREMs) for all patients in line with specified requirement (6 weeks following primary or revision surgery)
- The Contractor will provide a data solution service capable of capturing PROMS and PREMS data electronically and by postal questionnaire for defined patient cohorts across all joint types.
- The Contractor will store this data securely in a separate database for appropriate use, as directed by the NJRMT and adhering to the same obligations set out under section 5.2.1 above and NHS security standards and requirements
- The Contractor will provide a platform capable of delivering the required information service or make appropriate arrangements with any third party, including appropriate licensing to PROMs instruments. These solutions (including any linked systems) must comply with all relevant data protection legislation and guidelines, in particular the Data Protection Act 2018 and the Common Law Duty of Confidentiality.

Service level requirements:

- PROMs questionnaires should be successfully delivered to 90% of patients within 1 month of the specified time points
- Returned PROMs data should be available from the registry within 1 month of return by the patient

Key outputs:

- Extracts of PROMs data to be provided to the NJR statistical analysis, support and associated services Contractor as required for key analysis (twice annually for outlier analysis, annually for annual report analysis) and broader activity such as research
- Extracts of PROMs data to be provided to other third parties such as external research groups as directed.

5.2.1.5. Validation system

- The Contractor will work with the NJRMT and NJR sub-committees to ensure that data entered through any agreed data entry systems (bulk upload, web portal or component database) passes a set of rules.
- These validation systems should be appropriately configures to ensure that all data entered is credible
- Validation and management systems will assure data quality both retrospectively and prospectively. New system rules will be applied to retrospective data where appropriate.
- The Contractor will deliver regular validation reporting to users and the NJRMT and ongoing monitoring of systems and rules to proactively improve them
- The data entry system, component database, and bulk upload all have business rules built into them. The number of complex business rules built into the data entry system ensure that the combinations of components entered are credible and in line with how components are commonly used.
- These systems shall prevent the entry of data that does not meet:
    - Commonly accepted data format checks (e.g. postcode, numeric data in non-numeric fields, telephone numbers correctly formatted with STDs)
    - NJR's business rules for credibility.
- Data failing to be entered should be reported on (including reasons for failure) both to the units (to allow them to correct the mistakes) and to the NJRMT (to allow it to check its business rules). NJR expects the Contractor to monitor these systems and rules and to proactively improve them as is required to improve the quality of the NJR data.
- NJR requires the Contractor to conduct systematic audits on units to ensure quality of data is aligned with the objectives of NJR data quality strategy. The NJRMT also reserves the right to have data audits conducted at its discretion by other organisation(s) as appropriate.

Service level requirements:

- 100% of records meet minimum data requirement
- 100% of records will meet HQIP business rules

Key outputs:

- For the web portal, bulk upload and component database, monthly reports detailing
    - Entry method breakdown
    - Data format failures
        - Overall percentage
        - Detailed breakdown of reasons for failure
    - Business rule failures
        - Overall percentage
        - Detailed breakdown of reasons for failure.

5.2.1.5.1. Business rules

- Data entry business rules will be implemented across all data capture systems to reduce the likelihood of incorrect data entry.
- Business rules should be updated following each dataset review to ensure that new and modified data items are accounted for in the data validation
- Business rules for compatibility of components should be carefully considered to reflect current surgical practice and clinical recommendations. This system should have an 'override' facility to allow entry of components where a non-recommended combination is included. Use of the override facility must be logged and data reported to the NJRMT and relevant NJR sub-committees
- Business rules should be consistent with those used by the implant compatibility scanning tools (section 5.2.3.2.3)

5.2.1.5.2. Data quality audit programme

- The contractor will deliver an ongoing programme of data quality audits across all joint procedures captured by the NJR.
- The data quality audit system will be automated and will involve upload from hospitals of an extract of data from their PAS system, which will be automatically compared with NJR submissions for the same unit. Hospitals will then be encouraged to identify missed records and enter them retrospectively.
- The contractor will support the management for the Data Quality Provider Awards programme for units with high rates of submission
- The contractor will provide dedicated data quality staff to support hospitals with participation in the data quality audit and in identifying missed records
- The contractor will provide periodic (no less than quarterly) reports on the data quality audit programme including metrics representing pre and post audit compliance rates at unit, Trust and national levels.
- The contractor will support ad hoc data quality audits as directed by the Data Quality Committee to explore and correct specific areas of data quality concern (for example, a

spotlight on reverse shoulder arthroplasty). Ad hoc audits of approximately two areas are anticipated per annum.

5.2.1.5.3. Reporting of potential surgical never events

- The contractor will use NJR business rules (see section 5.2.1.5.1) to identify cases of potential surgical never events (mismatches of side and/or size of components and use of 'mix and match' head and stem combinations for hip arthroplasty). This will apply to both fully submitted records and 'draft' records in the edit stack.
- Identification of components that are missing for the system should be dealt with as a data quality process separate from this mismatch process.
- The contractor will work with the submitting unit or surgeon to identify if these issues represent a data quality issue, or if a genuine never event has occurred.
- In the event of a genuine never event, escalation to the NJRMT and NJR Surgical Performance Chairman will be undertaken. Cases will also be escalated due to lack of response to initial contacts.
- Periodic reports of never event rates should be provided to Data Quality and Surgical Performance Committees.
- Reporting of never events will interface as appropriate with the implant safety scanning tools described in section 5.2.3.2.3 and any new tools developed during the contract term.

5.2.1.6. Component database

The data entry system uses reference data within the associated structures of an NJR component database to help ensure validity. The Contractor will monitor and maintain the component database systems and rules on an ongoing basis to ensure they are relevant to current practice and proactively improve them as is required to improve the quality of the NJR data and keep pace with evolving practice.

5.2.1.6.1. Data capture

- The Contractor will provide a dynamic web form to industry users to allow completion of component classification data to a dataset agreed by the NJR.
- The contractor will be responsible for working with industry to ensure completion of dataset attributes to a high level
- The data capture system will be updated to reflect dataset changes specified by the NJR as required, and users supported in retrospectively completing any new attributes introduced.
- The contractor will provide staff to support and liaise with industry to maximise engagement.

Key outputs:

- The Contractor is required to provide a facility by which manufacturer product portfolio changes can be uploaded to the component database
- The Contractor will maintain and update an implant supplier list along with contacts for each company.

Service level requirements:

- A minimum dataset of attributes agreed as essential by NJR will be completed for all currently used implants within 1 months of first use
- A minimum dataset of attributes agreed as essential by NJR will be completed for 75% of legacy implants within the first year of the Contract, increasing to 100% by the second year and maintained at 100% thereafter
- A complete dataset of attributes will be completed for all currently used implants within 3 months of first use
- A complete set of attributes for all legacy will be maintained at 90%

5.2.1.6.2. Data outputs

The Contract will use attributes from the component database to produce datasets for outlier analysis and the NJR Annual Report. Component database attributes will also be used to populate NJR Supplier Feedback systems.

5.2.1.6.3. Alignment with EPRD/ISAR/RIAP

- The Contractor will implement any periodic changes to the component databases for all joints to ensure alignment with the equivalent databases maintained by the German Arthroplasty Registry (EPRD) and the ISAR International Prosthesis Library (IPL).
- At the direction of the NJRMT, the Contractor will liaise as necessary with other international databases such as RIAP and undertake activities necessary for potential participants wishing to join the NJR Component Databases.
- The Contractor would be expected to pass on to the third party registry, any additional costs that may occur in respect of this activity.

5.2.1.6.4. Developments

- The Contractor will undertake a component database development/upgrade that will allow for
  - Processing of Unique Device Identifiers/Global Trade Item Numbers (GTINs) alongside existing manufacturer component catalogue numbers for all implants
  - Development of a full component classification for elbow and ankle implants including the development and implementation of the classification architecture
  - Expansion of the component classification for hip implants to include hip hemiarthroplasty and endoprostheses used for tumour surgery.

5.2.1.6.5. Root and branch review of implant brands

- The contractor will, during the first year of the Contract, work with the NJR statistical services, solutions and associated services Contractor and the NJRMT and relevant sub-committees to define a reporting unit for hip, knee and shoulder implants to be used consistently across the NJR in place of ‘implant brand’
- The contractor will implement reporting unit into the component database and ensure that all related reporting systems, including supplier feedback and outlier extracts are based on this field.

- Equivalent exercises for elbow and ankle implants, hip hemiarthroplasty and tumour endoprosthesis will be undertaken as part of the database development for those areas.
- The Contractor will conduct a repeat review of all implants every 2-3 years to identify where changes need to be made to enable reporting of implant performance at a more granular level.
- NJR expects the Contractor to monitor these systems and rules and to proactively improve them as required to improve the quality of the NJR data.
- The Contractor is required to provide the necessary expertise in order to carry out its role, including appropriate knowledge of the classification of orthopaedic implants used in joint replacement surgery
- A strategy should be put in place to ensure that any future implant variants can be examined in a granular way, and that any additional sub-strata can be examined easily.

5.2.1.7. Secure storage of procedure data

Procedure data shall be stored in a secure and encrypted format on an enterprise level relational database system (referred to henceforth as the Data Storage Platform). This Data Storage Platform will be in line with the recommendations of the Electronic Service Delivery *Electronic Government Services for the 21st Century* (www.cabinetoffice.gov.uk) and Electronic Patient Record requirements.

The Contractor shall be responsible for all aspects of the security, management, back-up and restoration, maintenance of the Data Storage Platform as well as its enhancement with new features as required by NJR

As a minimum requirement the Data Storage platform will provide

- Secure storage of procedure data and other NJR captured data
- A full audit trail of data input, processing and output activities
- A link with data from the Personal Demographics Service (PDS) and/or civil registration data to permit detection of patients on the registry who have died
- The Contractor is registered with the Data Protection Public Register
- The Contractor is registered with the Information Commission and is certified to ISO 27001
- The Contractor has a satisfactory score according to the Data Protection and Security Toolkit
- The Contractor has achieved Cyber Essentials certification
- The Contractor can demonstrate that its existing working practices are in line with best practice recommended by the cyber security framework and will continue to change and update its systems and working practices to demonstrate adherence on an ongoing basis

Service level requirements:

- Data Storage Platform must be available to query and receive data 99.5% of the time.

Key outputs:

- Report of total number of records stored
- Report of number of new records by implant type received in last calendar month
- Breakdown of system issues by type including system downtime, data corruption and security breaches.

5.2.1.8. Reconciliation (linkage) of data with other healthcare datasets

- The Contractor will arrange and maintain a routinely available link with data from the Personal Demographics Service and/or Civil Registration data to permit detection of patients on the registry who have died
- In addition, the Contractor will develop and maintain system(s) to allow for the reconciliation (linkage) and comparison of data with other national and external datasets including but not limited to those detailed below:
    - Hospital Episode Statistics Database England (HES)
    - Civil registration data
    - Patient Episode Database Wales (PEDW)
    - National and NJR-delivered Patient-Reported Outcome Measures (PROMS)
    - Orthopaedic Data Evaluation Panel (ODEP) ratings data
- It is anticipated that future requirements will include:
    - Independent sector dataset(s)
    - UK Biobank, the Clinical Practice Research Datalink and other relevant research datasets
    - Other national clinical audits and registries including the National Hip Fracture Database and the British Orthopaedic Association TORUS registries (British Spine Registry, the National Ligament Registry (NLR), the UK Knee Osteotomy Registry (UKKOR), the Non-Arthroplasty Hip Register (NAHR), the Bone and Joint Infection Registry and audits led by BSSH and BOFAS)
    - Other national devices datasets including but not limited to the Medical Devices Information System and classification systems maintained by MHRA.
    - Other national and international datasets including those from European and International device registries
    - Clinical trials databases
    - Data from other geographical systems

- All and any systems developed for linkage reconciliation and comparison should be capable of being integrated with other as yet unknown data sources which will form part of separate business case approvals, as directed by the NJRMT and governed by the NJRSC.

Service level requirements:

- >95% of mortality data is to be linked
- >90% HES/PEDW data is to be linked
- Data must be reconciled within one month of receipt
- Data for the purpose of the NJR Annual Report must be reconciled for use as outlined at section 5.2.2.4

Key outputs:

- For each data reconciliation source e.g. HES, PEDW
    - Number of records received
    - Number of records imported
    - Time taken to import

- Failure rate and detailed analysis

5.2.2. Dataset production

5.2.2.1. Production and publication of standardised datasets and reports

The Contractor is required to prepare periodical (that is, monthly, quarterly, bi-annual, annual and ad-hoc) standardised datasets and reports for analysis and publication at the direction of the NJRMT. These include but are not limited to the following:

- Percentage compliance
- Percentage patient consent
- Linkable percentage rate through valid NHS numbers or national patient identifiers
- Production of a potential outlier dataset for further analysis by the NJR statistical analysis, support and associated services Contractor
- Production of a linked dataset for further analysis by the NJR statistical analysis, support and associated services Contractor
- Production of a dataset for 'research-ready' standardisation and development in conjunction with the NJR statistical analysis, support and associated services Contractor
- Production and publication of ad hoc datasets including individual subject access requests under the terms of the Data Protection Act, 2018
- Production and publication of all datasets as currently available online on and through the NJR website to meet stakeholder information needs including data required for the validation of Best Practice Tariff compliance .

In addition the Contractor will also provide a flexible business operation capable of delivering updated analysed NJR datasets and information to stakeholders on both a continuous and ad hoc basis. This should include secure transfer of complete datasets.

5.2.2.2. Production of potential outlier datasets

- The Contractor is required to produce pseudonymised (only identifiable by a unique number) potential outlier datasets for analysis by the Statistical analysis, support and associated services contractor biannually. The dataset must only be provided in the exact format specified. Any changes to the format of the file must be approved in writing by the NJRMT.
- The Contractor will provide an ongoing development and management of a related continuous monitoring system capable of providing performance information from the Statistical analysis, support and associated services contractor on outlier data for implants, units and surgeons to a range of stakeholders using an NJRSC approved methodology.
- The Contractor will manage the ongoing development of outlier data files as an iterative process alongside and in conjunction with the Statistical analysis, support and associated services contractor.
- If the Statistical analysis, support and associated services contractor identifies any potential outliers that require further actions and contact – the Contractor shall provide the list of unique reference numbers for discussion at the Surgeon Performance Committee following which the NJRMT will carry out the necessary administrative process to communicate outlier status via a related Outlier Management system.

Service level requirements:

- Production of the Potential Outlier Report to a format specified by NJR, at present this is produced bi-annually. Frequency of the production is subject to change as requested by the NJR Surgeon Performance and Implant Scrutiny -Committees and directed and approved by the NJRMT.
- Delivery of datasets on time and according to a pre-determined specification will be a deliverable linked to payment. Non-conformance will result in reduced payments being made to the Contractor. Persistent non-conformance will be considered a serious breach of contract.

Key outputs:

- To produce an initial potential outlier dataset report in a format that is easy to read and interpret. The report will be available in electronic and hard copy format as required and transferred securely.

5.2.2.3. Production of ad hoc datasets: data requests and research

- NJR currently deals with approximately 200 ad-hoc data requests per annum. A proportion of these are requests for additional data, a proportion of these address Freedom of Information (FOI) requests and the remainder comprise data intended for research purposes.
- A three-stage approach is required to manage all ad hoc data requests.
    - Step 1: the Contractor logs, assesses and clarifies the ad hoc data request for cost and impact, then grades the request accordingly and sends to the NJRMT to review for approval
    - Step 2: The NJRMT assesses the ad hoc data request, then approves or rejects it
    - Step 3: the Contractor actions the approved ad hoc data request.
- Service level requirements: Will allow for processing within the stipulated timescale but clock will stop where delays in processing are caused by the requester e.g. further information required from requester
- The Contractor is required to grade and assess ad hoc data requests within the following timeframes:
    - FOI Request – process within 1 working day
    - Standard request – process within 5 working days
    - Intermediate request – process within 10 working day
    - Complex request – process within 15 working days.
- The Contractor is required to action the ad hoc requests within the following timeframes:
    - FOI Request – process within 2 working days
    - Standard request– process within 5 working day
    - Intermediate request – process within 10 working days
    - Complex request – process within 15 working days.
- In order to reduce the burden of this volume of data requests, the Contractor will be required to develop a platform that allows a hospital unit to download their own record level data from the NJR themselves.

5.2.2.4. Production of the NJR Annual Report datasets and linked datasets

- The Contractor will produce NJR Annual Report datasets and linked dataset for the Annual Report and additional stakeholder information services. This will include but is not limited to:

    - The content of the datasets
    - The date range to include for each dataset
    - The date by which the relevant datasets are required including datasets for the Statistical analysis, support and associated services contractor.
- The dataset must only be provided in the exact format specified. Any changes to the format of the file must be approved in writing by the NJRMT. Notice of any changes to the datasets required will be given to the Contractor in advance
- The Contractor will maintain and submit a catalogue of changes to the NJR statistical analysis, support and associated services Contractor.
- The Contractor is required to produce, annually, a linked dataset comprising HES, HES-Civil Registration and HES-PROMs data (see section 5.2.2.4). The Contractor is required to produce this in accordance with information governance requirements.
- The Contractor will be required to develop and implement mechanisms on an ongoing basis to collect and use additional outcomes aside from revision data. This is likely to include PROMs (from national PROMs data)and PREMS, non-revision reoperations (including but not exclusively dislocation, periprosthetic fracture fixation, conversion to fusion, excision, manipulation under anaesthetic, amputation) and other post-operative complications available, for analysis and reporting to reflect the range of ways joint replacements could fail.
- Contractors are invited to outline details of the mechanism(s) by which they would capture, exploit and integrate HES data into NJR outputs to provide analysis of additional outcome measures the NJR seeks to understand and report on. Details should include how this mechanism can be implemented routinely.
- The Contractor is required to work closely with the NJRMT and the Chair of the NJR Editorial Board and attend all NJR Editorial Board meetings as required to support the timely production of the NJR Annual Report.
- Preparation of the report typically starts 9 months prior to the publication date (which is usually during the month of September) with an associated period of review following its publication.
- The Contractor is required to manage the process for delivery of sections of content for inclusion in the NJR Annual Report, scheduled in agreement with the NJRMT. This may include but is not limited to:
    - Standard data analysis in relation to overall progress in relation to KPIs (compliance, patient consent and record linkability between the NJR and HES/PEDW databases including at unit-level)
- Standard data analysis in relation to periodical clinical activity. The contents of these sections (commonly known as Part One, Two, Four and appendices including prostheses used in joint replacement) will then be provided to the NJR Annual Report Project Manager and NJRMT for editing and inclusion in the report, before passing to the Editorial Board for approval The Contractor will be required to demonstrate its vision for expanding and embedding the use of health economics analyses to provide added value to NJR outputs.

Key outputs:

- Production of high quality, accurate and timely drafts of required sections as directed by the NJRMT and the Chairman of the NJR Editorial Board.
- Further information on the NJR Annual Report can be found at www.njrreports.org.uk
- Please see section 5.5 for further optional requirement for an NJR Annual Report Project Manager in relation to the production of the NJR Annual Report.

5.2.2.5. Best Practice Tariff (BPT)

- The Contractor is required to provide a quarterly report for publication at www.njrcentre.org.uk to assist units in the validation of Best Practice Tariff for NHS-funded hip and knee procedures. NJR compliance and patient consent data forms part of the tariff requirement in England. The Contractor may be required to extend this reporting to additional joints that may be affected in the future, as directed by NHS England/Improvement (NHSEI) and the NJRMT.
- The Contractor will be required to implement changes to reporting of Best Practice Tariff compliance where changes are made by NHSEI to the indicators. Review of the indicators is conducted on an annual basis.

5.2.2.6. Patient Decision Support Tool

The Contractor will provide an annual clean dataset for the Patient Decision Support Tool https://jointcalc.shef.ac.uk/ according to a specification provided by the University of Sheffield.

5.2.2.7. Development of a consolidated production method of capturing of NJR Data

Currently there are different data outputs derived from different extracts of NJR data which can result in slightly different interpretation of the data. There is scope for refining the current process of data collection and cleaning.

- The Contractor will be required to work with the NJREC, NJRMT and NJR statistical analysis, support and associated services Contractor to support and contribute to the development of routines to collect and process data which will enable the application of cleansing, processing and analysis within a single environment for use as a sole source by all relevant stakeholders. Delivery of the agreed routines will take place within the first six months of the contract. A specification outlining the Contractor's role in delivery of this activity will be provided on award of the contract
- The Contractor will create and regularly update such data management documentation required to illustrate data management activities This will include, but is not limited to, data preparation guidelines, Standard Operating Procedures and an outline process flow of all the steps undertaken to clean and process the data
- The Contractor will provide data cleansed to the standard and in the format specified by the NJR statistical analysis, support and associated services Contractor
- The Contractor will notify the NJRMT immediately of any instance where data does not match after cleaning has taken place and work with the NJR statistical analysis, support and associated services Contractor to resolve any inaccuracies or differences within the data
- The Contractor will work closely with the NJR statistical analysis, support and associated services Contractor to reduce duplication of cleaning steps and maintain a consistent approach to reporting.
- The Contractor will work collaboratively and constructively with the NJRMT and NJR statistical analysis, support and associated services Contractor and agree the final dataset which will represent the main source for all data outputs and published data, including onward sharing of the dataset with third parties.

- Once a specification for this work programme is agreed, the Contractor will work to agreed timescales, delivery outputs and update frequencies as directed by the NJRMT.

5.2.3. Information for patients, surgeons, units and manufacturers

- The NJR requires a fully managed data solutions service to support and increase accessibility and use of data by NJR stakeholders. This includes the hosting, maintenance, management, development and data processing associated with stakeholder information services available on, at or through www.njrcentre.org.uk and/or NJR Connect Data Services.
- The Contractor will proactively review the solution to put forward suggestion for upgrades to the look and functionality of all outputs.
- Data in the NJR database should be retrievable by users and stakeholders for appropriate purposes at an appropriate level.
- The Contractor is required to provide a flexible business reporting/performance management system allowing such retrieval of data by users. These should be regularly updated on a continuous basis (that is, monthly, quarterly, bi-annually and annually as required)
- The Contractor will ensure the system is configurable to update geographical aggregation of results to reflect any relevant regional changes as they are introduced across the healthcare system during the period of Contract.
- There is scope to implement the reporting of shoulder, elbow and ankle joint outcomes. The Contractor will be required to collect and supply the data for these additional joints for analysis and reporting in the event that this is required. The use of this data will be subject to the direction of the NJRMT.
- The Contractor is required to participate and advise, as necessary, on the appropriate development and use of the data in accordance with the NJR Strategic Plan and Annual Work Plan.
- It is the responsibility of the Contractor to provide a data solution service capable of delivering the required information services or to make appropriate arrangements with any third party, including any necessary licensing.
- Solutions (including any linked systems) must comply with all relevant data protection legislation and guidance including the Data Protection Act 2018 and the Common Law Duty of Confidentiality.
- The Contractor is required to routinely provide, maintain and update a series of reports and web-based applications available which provide information for use by various NJR stakeholder groups in conjunction with requests as conveyed or approved by the NJRMT
- The Contractor will also be required to routinely develop and implement system updates to ensure reporting reflects stakeholder needs as determined, discussed and approved by the NJRMT and relevant NJR sub committees.

5.2.3.1. Information for patients

- The Contractor is required to process data to present and develop the reporting of surgeon and hospital activity and outcomes data via NJR Connect Data Services and the NJR Surgeon and Hospital Profile website.
- The Contractor is required to make available to surgeons, a view of the data for publication (at surgeon-level only) in advance of publication
- The Contractor will provide individual surgeon and unit activity and outcomes into the public domain annually and in liaison with the NJR statistical analysis, support and associated services Contractor.

Key outputs:

- The Contractor is required to publish individual surgeon and unit activity and outcomes into the public domain annually and in liaison with the NJR statistical analysis, support and associated services contractor

5.2.3.2. Information for clinicians

5.2.3.2.1. NJR Clinician Feedback

NJR Clinician Feedback is provided via NJR Connect Data Services, a portal where each surgeon can access their own and comparative data. The Contractor is required to process data to implement and develop the reporting of individual surgeon data. Updates to the system will be agreed with NJR and implemented annually. As part of the core service provision, the contractor is required carry out annual revisions to include new metrics and presentations of data and revisions to existing metrics and presentations

Key outputs:

- The Contractor is required to provide and refresh clinical activity data on a daily basis
- The Contractor is required to provide and refresh outcomes data on a six-monthly basis, in liaison with the NJR statistical analysis, support and associated services contractor

5.2.3.2.2. NJR Consultant Level Report

NJR Clinician Feedback, provided via NJR Connect Data Services, allows surgeons access to a NJR Consultant Level Report (CLR) – a standard individual report comprising clinical activity and outcomes data to assist appraisal and revalidation. Annual changes to CLR to introduce new presentations of data and modification of existing metrics are required to be implemented as standard. Updates to the system will be agreed with NJR and implemented annually.

Key outputs:

- The Contractor is required to provide and refresh NJR Consultant Level Reports annually.
- The Contractor is required carry out annual updates as part of the core service provision

5.2.3.2.3. Implant safety scanning tools

- The contractor will maintain access to a range of tools that allow surgeons and surgical teams the ability to scan implants prior to surgery and use the NJR business rules (see section 5.2.1.5.1) to assess the compatibility of these components.
- This service should be delivered using a range of platforms to suit user needs, but as a minimum should consist of (a) an Application Programming Interface (API) to allow integration with hospital Scan for Safety and other theatre systems (b) a web based application compatible with direct data entry and scanning using a handheld scanner (provided by the hospital) (c) a mobile application to allow scanning of implant barcodes using the camera of a smartphone or other handheld device (IOS and Android to be supported).

- The system should assess mismatches of side for hip and knee components and size for hip components. It should also identify mismatches of manufacturer between head and stem implants.
- The system should be further developed to identify mismatches based on size of knee implants, laterality of unicondylar knees, shoulder constructs and other metrics as defined by the NJR.
- The contractor should develop the system to allow automatic population of data entry to both the NHS and Independent sector systems from the application where the hospital require this service. This should permit manual edits following population.

5.2.3.2.4. Library of implant reports

The Contractor is required to make available to surgeon users, via NJR Connect Data Services, copies of Summary and Post-Market Surveillance Reports (see section 5.2.3.4.1) for all implants and implant combinations that have been used in NJR hospitals in the previous two years.

5.2.3.2.5. Surgeon notifications

- The Contractor is required to action appropriate notifications for surgeons in the following events
    - The death of an operated patient within 90 days of surgery
    - The revision of an operated patient
    - The use of level 1 outlier implant
    - The identification of a potential surgical never event
- Notifications should be by both email and NJR Connect Data Services. Email notifications should direct users to NJR Connect to view patient details.

5.2.3.3. Information for healthcare providers

5.2.3.3.1. Data downloads

The Contractor will develop an interface that will allow authorised hospital users to extract identifiable record level data, linked with outcomes, on their patient cohort in a range of formats (XLS, CSV, PDF).

5.2.3.3.2. NJR Management feedback

NJR Management Feedback, provided via NJR Connect Data Services, is a portal through which each hospital unit can access their own and comparative data. The Contractor is required to process data to present individual unit activity and outcomes (mortality, revision and PROMs). Updates to the system will be agreed with NJR and implemented annually.

Additional development to the Management Feedback system to produce reporting at the following levels is required:

- NHS Trust (England), Health Board (Wales) and Health and Social Care Trust (Northern Ireland)
- Independent sector hospital groups
- Sustainability and Transformation Plan (STP) or Integrated Care System (ICS) footprint
- NHS England regions
- Revision networks, formal and informal groupings of hospitals and other entities to be defined by the NJR

As part of the core service provision, the contractor is required to carry out annual revisions to include new metrics and presentations of data and revisions to existing metrics and presentations

Key outputs:

- The Contractor is required to provide and refresh clinical activity data on a daily basis
- The Contractor is required to provide and refresh outcomes data on a six-monthly basis, in liaison with the NJR statistical analysis, support and associated services contractor.

5.2.3.3.3. Annual Clinical Report

- NJR Management Feedback, provided via NJR Connect Data Services, allows healthcare providers access to a NJR Annual Clinical Report (ACR) – an annual report of clinical activity and outcomes data for the unit and surgeons. The Contractor is required to provide access to authorised users.
- Annual changes to ACRs to introduce new presentations of data and modification of existing metrics are required to be implemented as standard. Updates to the system will be agreed with NJR and implemented annually.
- The Contractor will record and maintain up to date details of all authorised users including those who have delegated/requested authority. These users should receive notice of publication of the ACR.

Additional development to the ACR production is required to produce reporting at the following levels:

- NHS Trust (England), Health Board (Wales) and Health and Social Care Trust (Northern Ireland)
- Independent sector hospital groups
- Sustainability and Transformation Plan (STP) or Integrated Care System (ICS) footprint
- NHS England regions
- Revision networks, formal and informal groupings of hospitals and other entities to be defined by the NJR

Key outputs:

- The Contractor is required to provide and refresh an NJR Consultant Level Report annually.
- The Contractor is required carry out annual updates and amends as part of the core service provision

5.2.3.3.4. Implant price-benchmarking service

- NJR Management Feedback provides a secure web portal where NJR data can be associated with unit-level implant pricing data. Unit-level implant pricing data is submitted to the system directly by units themselves.
  The Contractor is required to work with the NJR to ensure that pricing data entered by the unit shall pass through a set of validation systems. These systems shall prevent the entry of data that is (not exhaustive):
  - Not correctly attributed to a valid procurement unit
  - Has invalid dates and related to invalid products
  - Relates to invalid devices.
- The Contractor is required to send error reports to providers should these rules not be met.

- The Contractor is required to provide access to one authorised user per unit with the potential to increase authorised users. The Contractor should outline appropriate licensing options in their core costings.

- The Contractor will record and maintain up to date details of Trusts status with regard to the annual upload of pricing data. These users should receive notices and reminders of their upload status to encourage annual pricing uploads. The Contractor will work with Trusts to encourage uploads of up to date pricing information

Key outputs:

- The Contractor is required to provide and refresh a unit's implant pricing report on each submission of unit implant pricing data
- The Contractor is required to extract implant pricing data for appropriate use, as directed by the NJRMT and transfer the data securely, as per standards outlined in section 8.
- NJR Implant Price-benchmarking offers two service levels – a base service known as INFORM and an enhanced service known as EMBED both of which are available and provided to all NHS units as part of their annual subscription charge. The EMBED service is also available to independent units for a second, additional subscription charge. The Contractor is required to support end-users in their use of the system.
- The Contractor is required to provide regular progress and status reports showing the percentage increase in trusts uploading annual implant pricing upload and activity undertaken to encourage upload at Trust level.
-
- T The Contractor will work with NJR to propose and implement appropriate service models in order to develop and enhance the function of NJR Implant Price-benchmarking including its use in providing data and reporting on the cost effectiveness of joint replacement.

5.2.3.3.5. Product safety notifications

The Contractor will monitor MHRA safety notices for relevant product safety notices and recalls. Upon identification of a relevant notice, the Contractor will notify the NJRMT and NJR Surgical Performance Committee chairman and supply all participant units with a list of patients who have been implanted with the implant subject to the safety notice.

5.2.3.4. Information for suppliers (orthopaedic implant manufacturers)

5.2.3.4.1. NJR Supplier Feedback

- The NJR Supplier Feedback function provides a secure access data portal for suppliers to view data relating to their own product range. As part of the NJR's economic model for financial sustainability launched in April 2014, orthopaedic implant suppliers make a financial contribution to the NJR for provision of the NJR Supplier Feedback system to support post-market surveillance.
- NJR Supplier Feedback offers two service levels – a core service and an enhanced service with additional data reporting and capture features. At the discretion of NJR, the two levels are accessible through a fixed-fee and variable arrangement with the latter currently provided for through a revenue-sharing arrangement with the Contractor. NJR invites prospective

Contractors to propose appropriate service models in order to develop and enhance the function of NJR Supplier Feedback.

- The Contractor will be responsible for collecting subscription fees from industry users in respect of Supplier Feedback subscriptions. HQIP will issue an invoice in respect of recovery of these fees. Standard commercial terms for payment are 30 days in arrears in line with terms set out on the invoice.

Key outputs:

- The Contractor is required to provide and refresh clinical activity data on a quarterly basis
- The Contractor is required to provide and refresh outcomes data on a six-monthly basis, in liaison with the NJR statistical analysis, support and associated services Contractor.
- The Contractor is required to provide reports detailing breakdown of supplier income received on a quarterly basis
- The Contractor is required to work with NJR to administrate and facilitate provision and supplier use of the service. This will include, but is not limited to:
  - Calculating and reviewing charging proposals annually and on an ongoing basis
  - Continue to develop the data service and make recommendations for service improvement
  - Proactive promotion of the service and its benefits.

5.2.3.5. Multi-stakeholder information and statistics

5.2.3.5.1. NJR StatsOnline

- NJR StatsOnline provides hospital-level data for whole calendar months and is a web-facility for viewing and downloading NJR statistics. The service will be accessible via a platform hosted by the Contractor to enable ease of information update from the NJR data warehouse.
- The user interface of StatsOnline should be reviewed annually to ensure the system's regional search functionality is consistent with current NHS geography.

5.2.3.5.2. Online Annual Report

- In addition to the NJR Annual Report datasets and associated content (see section 5.2.2.4), the Contractor is required to process data, present and develop digital Annual Report content including hosting of www.njrreports.org.uk.
- Additional customisable reporting tools (in an equivalent style to NJR Connect Clinician and Management Feedback) are expected to be made available in the public domain. The exact metrics to be reported will be directed by the NJRMT.

5.2.4. User helpdesk user support and notification service

5.2.4.1. NJR Service Desk

The Contractor is required to provide a helpdesk service which is accessible by telephone and email during office hours (minimum requirement of Monday to Friday, 9am to 5pm excluding Public Holidays). The Contractor is required to provide for out-of-hours availability for the benefit of stakeholders in exceptional circumstances as directed by NJR.

The NJR Centre service desk currently receives an average of 1500 calls per quarter. It anticipated that this may rise to an average of 1,800 calls per quarter over the contract period.

Service level requirements:

The Contractor's service desk will be the primary point of contact (via email, phone and post) for all end-users of the NJR Centre services and will provide the following:

- Minimum availability between the hours of 9am and 5pm for all working days
- The service desk shall answer 99% of calls received within 30 seconds
- Acknowledgement of all web queries (those relating to automated process within NJR systems e.g. password re-sets) within 30 minutes and
    - minor* incidents to be resolved within 24 hours
    - intermediate* incidents to be resolved within 8 hours and
    - critical* incidents to be resolved within 4 hours.
- Acknowledgement of all email queries within 15 minutes of being received and
    - minor incidents to be resolved within 24 hours
    - intermediate incidents to be resolved within 8 hours and
    - critical incidents within 4 hours.
- A first line resolution rate of 95%
- A log of all incidents, request and queries
- Advice and guidance on the use of and features of the NJR service
- Guidance to the end-users to prevent the recurrence of user related incidents on the NJR systems
- Information on the progress of incidents, requests and queries logged to the end users
- Timely processing of correspondence received from the NJRMT, the NJRSC and sub-committees
- Ability to facilitate and organise stakeholder feedback through a helpdesk function.

**Critical: NJR systems not available to end users (excluding and reason due to anticipated and communicated exceptions and downtime)*
**Intermediate: NJR systems not available to 60% of end users due to performance or capacity issues*
**Minor: It failure that impacts the NJR systems. Typically a critical function where a workaround solution is available, or a non-critical function where a work around is not available*
**Service request - request from a user or a user's authorised representative that initiates a service action enhancement or change as agreed as a normal part of service delivery eg reset password, provide, access to systems or information regarding applications /systems etc.*
**Incident: An event or unplanned interruption that result in interruption of one or more services e.g. unable to access services within the platform*

Key outputs:

The Contractor is required to provide a log of all incidents, requests and queries relating to the NJR service detailing, but not limited to:

- Volume of incidents
- Percentage of calls answered within 30 seconds
- Average time spent per incident

- Percentage of incidents resolved by support
- Analysis of problem areas resolved by support (e.g. cannot access data) to provide useful indicators for NJR training and help manuals
- Profile of all incidents by (total volume, volume by day, hour of day, functional area etc.)
- Analysis and profile of stakeholder responses following feedback exercises conducted through the helpdesk function.

5.2.4.2. Notification service

The Contractor is required to provide a notification service to support stakeholder use of, and access to data in the NJR. This will include but is not limited to:

- Coordinating and sending out NJR formal notifications via email or post including patient information leaflets/materials to support patient consent
- Extracting up-to-date stakeholder groups information from the contact database (section 5.2.5.5) for general communications purposes, in an appropriate format for data migration, as directed by the NJRMT.
- The Contractor will be required to provide a notification service as part of the core service in respect of any ad hoc notifications aligned to priority business requirements. Prior notice will be given when requests are made. Requests are infrequent.
- Over the previous and most recent contract period, the NJR has sent postal items, second class, at an average rate of 3,000 items per quarter. Additionally, patient information leaflets/materials are mailed at a rate of 22,000 per quarter across approximately 100-200 units. It is anticipated the requirement will continue to reflect recent distributions over the contract period however, demand is variable.

Key outputs:

- Maintaining and updating a stakeholder database with contacts for the purposes of coordinating and sending out formal notifications via email or by post.

5.2.4.3. Compliance officers

- The Contractor is required to provide sufficient NJR Compliance Officers (COs) (current provision is four COs) to provide direct on-site support to units and feedback to NJR on progress.
- Each CO will have responsibility for a regional area. The regional split will be in line with the NJR's geographical regional split which aligns with current NHS geography.
- The role of the COs is to work closely with the Regional Clinical Coordinators (RCC) to aid them in promoting the NJR, improving data quality and ensuring best practice in data collection, capture and validation.
- Particular emphasis should be placed on continuing to drive up compliance, but specifically to improving the overall data quality, accuracy and completeness as highlighted in the performance monitoring criteria below and outlined in the NJR data quality strategy.
- Other elements of the role include, but are not limited to:
    - Establishing and maintaining all relevant stakeholder contacts for all units
    - Promoting the aims of the NJR and facilitating good practice, data submission and data quality

- Analysing compliance, patient consent rates and other data quality indicators and actively working with units to improve underperformance against these key indicators
- Developing plans and actively working with poorly performing units, providing recommendations and assistance in the implementation of the NJR data quality strategy
- Providing data and reports for units, or assisting units in accessing NJR data for appropriate purposes
- Training new users in the data entry system and ensuring existing users are trained in new functionality
- Representing the NJR in hospital, regional and national meetings; and attending and exhibiting at conferences as directed by NJR, for example, British Orthopaedic Association and specialist society events; incorporating end-user training into the day where appropriate
- Facilitating meetings and delivering presentations and demonstrations as required
- Planning, organising and running NJR regional events taking direction from NJRMT as required, incorporating end-user training into the day where appropriate
- Feedback and escalation of comments, queries, problems and issues from the units to be actioned by the NJR Centre
- Responding to queries from units
- Maintaining contact at least quarterly with all NJR RCCs and discussing regular performance reports with them, as well as providing such progress updates for inclusion and discussion at RCC meetings
- Participating in the training and onboarding of new participants to the NJR
- Working with Trusts to encourage uploads of up to date pricing information to EMBED

- **Service level requirements:**

- Achieve minimum 95% compliance rate for their region
- Achieve minimum 90% patient consent rate for their region
- Achieve minimum 95% linkability rate for their region.

Key outputs:

- Quarterly report analysing unit-level activities undertaken against the above service-level requirements and solutions in meeting the targets
- Quarterly report analysing unit-level activities undertaken specifically in regards to assessing retrospective data submission and accuracy and other data quality checks
- Ad hoc reporting and provision of data to support the ongoing monitoring and implementation of the NJR data quality strategy.
- The Contractor is required to provide a senior lead resource to coordinate and manage the work of the Compliance Officers and oversee the implementation of required data quality work as determined by the NJR Data Quality Committee, and aligned to the NJR data quality strategy.

5.2.4.4. Training of end users (any NJR stakeholder using an NJR information service)

5.2.4.4.1. Training of end users

The Contractor is required to provide full training and produce appropriate training material and e - learning tools (see section 5.2.4.5) for the following:

- Unit staff to allow them to enter and amend data (prospectively and retrospectively) accurately and efficiently
- Any authorised staff/stakeholder to view and to generate the pre-defined reports through all NJR systems.

This training shall be in the form of training courses, one-to-one sessions and manuals (required to be available in both hard and electronic formats) as appropriate.

A training strategy should be developed and deployed in respect of any new tools or reports developed by the Contractor in the course of the Contract.

5.2.4.5. e-learning tools

- The Contractor should provide interactive e-learning tools to support users in using all NJR tools and systems provided under the Contract.
- These should be updated as new developments come on-stream and tested with users to ensure usability
- E-learning should include appropriate NJR branding in line with NJR brand guidelines and be signed off by the NJRMT prior to launch
- E-learning tools should be subject to regular review and updated with revised or new content as appropriate as services or training needs develop
- Data entry e-learning should be updated to reflect MDS updates (section 5.2.1.2)

5.2.5. Support to NJR Management Team and committees

5.2.5.1. Management of formal data collection and patient consent/data linkage licences and approvals

- The NJR will require the ability to change or update the data fields collected from units (minimum data set) with regards to orthopaedic procedures to perform further analysis and maintain clinical relevance.
- The NJR also requires ongoing use of patient personal data for outcomes analysis and datasets comprising linked patient records between NJR and other healthcare datasets.
- The Contractor is required to support the entire formal application process for the official approval from the appropriate assigned bodies in liaison with and for the approval of NJR for information governance purposes. Currently this is done on an annual basis. This includes applications to the HRA Confidentiality Advisory Group (separate research and non-research applications) and NHS Digital (annual application for record level data and three-yearly application for aggregate data).

5.2.5.2. Data sharing agreement support

- The NJR will require, from time-to-time, advice and administrative support from the Contractor in relation to data sharing agreements with national and international bodies. This is commensurate with the Contractor's involvement in processing data for the NJR.
- In the event of third party data security audit (for example by NHS Digital) the Contractor will fully cooperate with the terms of the audit under the direction of the NJRMT and supply any documentation required. The Contractor will make available a senior, suitably experienced lead to support the NJRMT with the conduct of the audit.

Key outputs:

- Successful provision of advice and administrative support in the formulation of appropriate data sharing agreements, as directed by the NJRMT.
- Provision of appropriate support and timely provision of accurate documentation as required during an audit

5.2.5.3. Additional advice and support to aid registry development

- The Contractor is required to review and keep abreast of the progress and development of the national devices registry programme and related initiatives or directives following the publication of the Cumberlege report and associated development of musculoskeletal (MSK) or orthopaedic registries and related initiatives that may take place.
- The Contractor is required to advise, as requested or when appropriate, the NJRMT and NJRSC on best practice developments in data management and data solutions that may be beneficial to the registry's development and service provision.
- The Contractor will develop and/or provide systems having the capability and the flexibility to expand to include other registries and develop musculoskeletal (MSK) registry databases if required.
- The Contractor will undertake any associated developments to existing systems such as mentioned in section 5.2.1.6 and any other general requirements outlined at section 5.3.

5.2.5.4. Brand Guidelines

- The Contractor will adhere to NJR brand guidelines and consult with the NJRMT for any further advice or clarification on these guidelines as required
- The Contractor will keep abreast of changes to the NJR brand guidelines and ensure updates are circulated to its relevant team members and adhered to as appropriate on all developmental activities or public facing media.

5.2.5.5. Contacts database maintenance

- A comprehensive list of contacts at NJR participant sites should be maintained by the Contractor and made available to the NJRMT. As a minimum, email, telephone and postal contact details should be maintained for the following groups:
    - All active surgeons
    - Data Entry staff
    - All other users with access to NJR systems
    - Hospital medical directors or Chief Medical Officers
    - Hospital Responsible Officers (where different)
    - Hospital Chief Executives
    - Hospital finance directors
    - Hospital pre-assessment unit staff
    - Implant manufacturers point of contact
    - Implant manufacturers regulatory lead

5.2.5.6. Data access portal

- In addition to the secure transfer of data noted at section 5.2.2.1, the Contractor will be responsible for carrying out an upgrade to the NJR Data Access Portal (DAP) to develop and implement the functionality to accept and process data and research applications electronically.
- This platform provides secure, online access by which approved stakeholders can access datasets for the purposes of research and other ad hoc data requests.
- The annual 'research-ready' dataset will be provided by the NJR statistical analysis, support and associated services Contractor which will then be linked by the Contractor with HES, Civil Registration and other external datasets prior to provision via the portal.
- Other datasets may be made available via the portal as instructed by the NJR.
- The Contractor will be responsible for
    - Populating the DAP with timely data. The data flow will be audited in line with NHS Digital requirements. The contractor will be required to ensure appropriate resources are available to carry out this requirement
    - Maintaining the integrity of the system, periodic updates to the hardware and software, managing and monitoring access to the portal for users and providing support for portal users.
    - Providing access for DAP users to appropriate software for data analysis, to include as a minimum latest version of STATA, R, Python and MS Excel.
    - Undertaking the data and software quarantine prior to upload on the system and prior to external release of outputs to the stakeholder.
    - Maintaining up to date and accessible end user audit records in order that NJRMT can monitor compliance in line with headline permissions
    - Reviewing portal use and outputs against approved research applications to ensure that use is consistent with approved project terms.

Service level requirements:

- Data Access Portal Platform must be available to query and receive data 99.5% of the time
- Notification to NJR within 5 working days where a portal user deviates from conditions of data access approval.

Key outputs:

- Fully maintained Data Access Portal Log to provide details of dataset upload, download, and dataset and software usage by portal user.

5.2.5.7. Outlier management system

- The Contractor should provide a platform to the NJRMT that will allow the monitoring of performance outliers (units, surgeons and implants).
- This system will allow the tracking of key dates and other relevant metrics and the tracking of responses against a timescale identified by the NJRMT and relevant sub-committees. The system should allow correspondence to be uploaded in a range of file formats.
- Direct access to read and edit data in the system should be available to the NJRMT, Surgical Performance and Implant Scrutiny committee chairman and NJR Medical Director.
- The system should be upgraded across the lifetime of the contract to reflect current outlier analysis groups. Implant monitoring should be introduced in year 1. Expansion to other joints should be introduced as these groups become subject to outlier analysis.

- The system should be upgraded to include a dashboard providing an overview of all outlier cases stored within the database.
- The system should be upgraded to allow integration with the contacts database to automatically generate notification letters based on a range of templates as provided by the NJR.

5.2.5.8. Surgeon new practice reporting

The Contractor should identify where surgeons who have been identified as performance outliers have begun a new practice at an NJR participant hospital and provide monthly reports to the NJRMT and NJR Surgical Performance Committee Chairman with any such cases.

5.2.5.9. Investigate the use of technology to detect signals and trends

As the NJR data evolves, it will look to use technology to identify patterns not observed previously. The Contractor is invited to provide feedback on what added value and experience it could bring with regard to exploring novel analysis methodologies or emerging technologies to bring value solutions to the dataset. This piece of work would most likely be run as a pilot project.

5.2.6. System requirements

5.2.6.1. Hardware

- To meet the cloud-based functionality requirements, the Contractor will maintain hardware capable of running the latest version of web browsers effectively, efficiently and without delay.

5.2.6.2. Software

- The NJR IT platform known as NJR Connect Data Services is provided by a cloud-ready, platform-based application framework solution. This platform is a flexible, portable application which enables use of open source / third party components. It is built as a generic model which can be configured to allow platform sharing for expansion to new entities (either on a stand-alone or fully shared basis) and integration with other healthcare datasets and data services through adoption of data standards where these exist. The platform-based architecture contains core features that support a broad range of clinical applications, including user management, security, audit, search, authentication, system administration, data integration and reporting services. The Contractor will be required to deliver and develop services using such a platform.
- The platform interoperability functionality should be in line with interoperability toolkit and guidance published by NHS Digital
- The Contractor will be expected to demonstrate effective and efficient cloud software experience with dynamically scaling server architecture that meets the NJR's processing requirements. The platform offering must be adaptable, extensible, manageable, and secure with real-time performance.
- The Contractor is responsible for the continual improvement of the user interface across all data solutions provided for the NJR. The Contractor is responsible for the delivery of systems interfaces that adhere closely to user requirements, visual digital preferences, best practice

and overall corporate branding. The Contractor is required to do this in collaboration with the NJRMT.

- At the end of the Contract term, the Contractor will be expected to support data migration of all relevant existing and future data in a usable format to a future supplier(s) as directed by the NJRMT.

Service level requirements:

The contractor will work with the NJRMT and the incoming Contractor to ensure migration of all data and systems within 20 working days of instruction.

5.2.6.3. Integration

- The Contractor will be required to work towards integration with Electronic Patient Records and other hospital IT systems during the term of the contract and will need to confirm the capability for this interoperability and associated costs of so doing.
- The Contractor will work to and keep pace as the NJR develops a long term IT integration strategy and road map in line with NHS Digital guidance around best practice. The Contractor will provide technical detail to support the development of this strategy as required.
- The Contractor will provide infrastructure and systems/platforms that are capable of interfacing NJR with national device databases and related NHS infrastructure as required across the term of the contract. The systems interoperability, should be in line with interoperability toolkit and guidance published by NHS Digital.
- The Contractor will ensure that the infrastructure/middleware provides functionality that complies with integration/interfacing standards that ensure that is capable of future collection or interface to obtain relevant data from third party systems.
- The Contractor will ensure that the infrastructure/middleware is able to manage data from A centralised collection point in whatever format data is provided and for that data to be subject to the same validation routines as directly entered data.
- The Contractor will routinely carry out horizon scanning activities to proactively identify, pre-empt and implement potential changes or activities that will require changes to infrastructure and/or platforms on a regular basis. All reasonable related costs of so doing to be borne by the Contractor.
- System must be compatible with all current accessibility standards, major browsers (Internet Explorer, Mozilla Firefox, Safari and Google Chrome) and must support both the current version and the previous major version (and all minor releases between versions).

5.2.6.4. Intellectual property

- Intellectual Property (IP) includes NJR web-based and/or cloud based data collection applications and information solutions available through www.njrcentre.org.uk and other NJR systems.
- The NJR software (including, but not limited to, data-storage platform, bulk-importer and data entry web-portal), database, datasets and other relevant IP belonging to HQIP will be made available under licencing arrangements to the incoming Contractor for use in the provision of the Contracted NJR data management, solutions and associated services. The Contractor will continue to maintain and develop these for the duration of the contract, and any IP generated in the course of providing the services will belong to HQIP.

- The incumbent Contractor holds the IP for its flexible business operation and performance management reporting system currently in use. The incoming Contractor will be required to provide a system such as this to drive NJR data systems and solutions in accordance with the requirements of the Specification. The incoming Contractor will hold the IP in its own pre-existing system, and will grant HQIP a licence to use it for the duration of the contract. At the point the contract ends all relevant NJR database/datasets etc. will be exported from the incoming Contractor's system in a useable format.

5.2.7. NJR website and related online information stakeholder services

- The NJR has a main, public-facing website (www.njrcentre.org.uk) to describe its purpose, share information for its stakeholder groups and provide details of all other NJR information services. It also acts as a hub for stakeholders for links to access other secure and non-secure data portals, which enable clinicians, NHS hospitals, independent healthcare organisations and implant suppliers to browse their own data. Responsibility for site development, content review and updates to this website is managed by the NJRMT, who will need to liaise with the Contractor at regular intervals with requests to review relevant Contractor-led content and associated documentation, so that it is kept up-to-date and that links to other Contractor-managed portals are functioning and maximised.
- All other portals will remain under the jurisdiction of the Contractor including NJR StatsOnline, NJR Surgeon and Hospital Profile, NJR Annual Report and secure data services via NJR Connect Data Services. All reviews and updates to these service platforms will be executed in liaison and collaboration with the NJRMT.
- The Contractor is responsible for the maintenance and continuous improvement of all NJR web-portals agreed to be within their remit and the Contractor should factor this into their costings as part of the core service. The Contractor is required to deliver an interface that aligns with and adheres closely to user requirements (visual and functional) and best practice and overall NJR branding, as advised. The Contractor is required to do this in collaboration with and according to guidance provided by the NJRMT.

Service level requirements:

- The Contractor will host and maintain all relevant NJR websites ensuring that that they are available at least 99.95% of the time
- The contractor will inform the NJRMT of any issues with any site immediately it becomes known.

Key outputs:

- The contractor will lead on the development of a collaboratively composed annual plan to outline intended web-portal user interface improvements and enhancements.

5.2.8. Escrow

- NJR require that the Contractor places the source code for all existing software (including but not limited to, data-storage platform, bulk-importer, component database, reporting platforms and data entry web-portal) into Escrow and that this stored source is updated whenever changes or additions are made to it. NJR also requires that the source code for any new elements or new programmes (be they either stand-alone or integrated) that it commissions the Contractor to develop are also placed in Escrow.
- This Escrow service shall provide the NJRMT or its authorised partners access for at least 3 years after the termination of the Contract and the entire cost burden of this shall be borne by the Contractor.

5.2.9. Performance monitoring criteria

- Any contract award will include performance-related key contract deliverables (payment linked deliverables).
- Payment linked deliverables will include but are not limited to deliverables associated with the release of accurate and timely release of extracts/data:
    a) Delivery of potential outlier datasets within an agreed timeframe and concordant with a prescribed specification
    b) Delivery of other standardised dataset reports within an agreed timeframe and concordant with a prescribed specification
    c) Delivery of datasets for the Annual Report as directed
- Performance of the Contractor shall be measured on but not limited to the following criteria:
    a) Availability of the data storage platform both for extraction of data and input of data by unit users, including the timely resolution of any issues affecting the platform
    b) Quality and availability of support and training to end-users
    c) Delivery of ad hoc analysis datasets to the time frame agreed for each piece of analysis
    d) Evidence of acceptable endeavours undertaken to ensure achievement of the data quality measures (see section 5.2.9.1 to 5.2.9.3). Compliance rate (95%), patient consent rate (95%) and linkability (95%)
- Performance and achievement against performance monitoring targets (compliance, linkability and consent) will be measured by the evidenced reporting to the NJRMT of the continuing processes and endeavours undertaken by the contractor to improve and achieve targets, inclusive of reporting and escalation processes.
- The NJRMT may include additional performance criteria (and associated payment linked deliverables) to ensure it is receiving best value for money and quality, during the contract period.
- The full range of performance linked deliverables and associated penalties will be agreed with the successful bidder prior to signing of the contract.

5.2.9.1. Compliance rate

- The Contractor is expected to ensure that the percentage targets for compliance, patient consent and linkability rates are maintained and reflected at national, regional and unit levels.
- The compliance rate is the number of procedures entered into the NJR compared with the number of procedures recorded by the NHS on for example Hospital Episode Statistics (HES) returns and Patient Episode Data Wales (PEDW) for the same period. The contractor will be required to measure, monitor and improve the compliance rate in order to maintain and further develop methods of validating data as appropriate.
- Currently, no appropriate data is available to carry out the same comparison for Northern Ireland or independent sector units. It is anticipated that will be a future requirement.
- The compliance target rate is 95%. The Contractor is required to increase the compliance rate to 98% always maintaining a minimum of 95% throughout the contract period.
- NJR expects the Contractor to be innovative and proactive in improving the compliance rate during the contract period and be able to evidence and demonstrate initiative and activity. More specific and detailed targets will be included in the Contract.

The Contractor is also required to provide a quarterly report for publication at www.njrcentre.org.uk to assist units in the validation of Best Practice Tariff for NHS-funded hip and knee procedures where applicable.

Service level requirements:

- Maintain the number of the relevant joint operations input into the NJR database at a minimum of 95%. The requirement is to meet this target quarterly as well as annually and across all operating units.

Key outputs:

Reports detailing:

- Percentage compliance rate for the reporting period
- Percentage compliance rate for reporting period versus previous periods
- Percentage average compliance rate for the quarter and year
- Activities undertaken and recommendations to improve compliance rate % (e.g. via Compliance Officers or other targeted activity).

5.2.9.2. Patient consent rate

- This is required to achieve the minimum patient consent levels for records submitted to the NJR. Patient consent is necessary in order to enter the personal patient details essential to enable the linkage of operation revisions to a specific patient and procedure.

Service level requirements:

- Maintain and improve the minimum patient consent rate of 95% quarterly and annually.

Key outputs:

Reports detailing:

- Percentage patient consent rate for the reporting period
- Percentage patient consent rate for reporting period versus previous periods
- Percentage average patient consent rate for the reporting period and year to date
- Activities undertaken and recommendations to improve patient consent percentage rate (e.g. via Compliance Officers or other targeted activity).

5.2.9.3. Linkability rate

- The total percentage number of joint replacement procedures that can be linked to other operations – linkable procedures - are the product of the following three percentages
    a) % of NHS procedures recorded in HES/PEDW also entered in the NJR (case ascertainment)
    b) % of procedures in a) for which consent was obtained
    c) % of procedures in b) for which NHS numbers were available
- This provides the linkable percentage - an estimate of all relevant procedures entered into the NJR that may be linked via an NHS number to other procedures performed on the same patient.
- This is required to achieve the minimum patient record linkable rate between HES and PEDW to NJR using valid NHS numbers and national patient identifiers.

Service level requirements:

- Maintain and improve the minimum annual linkability rate of 95% quarterly and annually.

Key outputs:

Reports detailing:

- Percentage linkability for the reporting period
- Percentage linkability for reporting period versus previous periods
- Percentage average linkability for the reporting period and year to date
- Activities undertaken and recommendations to improve linkability % rate (e.g. via Compliance Officers).

5.2.10. Annual development programme

Unless specified otherwise, all upgrades, developments and refreshes detailed within the contract specification are to be delivered as part of core services. In addition, the contractor is expected to deliver an annual development programme specified as part of the NJR annual plan. A range of £250k to £5million for possible development over the period of the Contract, with no guarantee of any development will be set aside for new development identified for delivery under the NJR Annual

plan and as part of the annual development programme. It is proposed to have an annual contract variation, based on the NJR's forecast that sets out clearly what the development cost will be and added to the core cost to give a revised payment schedule is for the year. Any unforeseen development not included in the annual plan would need a separate contract variation.

The Contractor is required to attend meetings to review, discuss and develop the specifications for areas of development. NJR reserves the right to use an 'intelligent customer' in the approval process for these works in order to ensure value for money.

5.3. Development and use of novel technologies

The Contractor will be called upon to progress the use of novel technologies to detect signals of underperformance. This may include but not be limited to the development and refining of Machine Learning and Artificial Intelligence (AI) models to identify patterns and signals in the data, to strengthen the early identification of patterns of poor patient outcomes.

The Contractors may also be invited to develop methodologies to detect poor performance based upon Patient Reported Outcome Measures (PROMs) data.

5.4. General requirements

The general requirements apply to all core and optional elements of work outlined in this specification.

5.4.1. NJRSC and NJR Sub-committees

- The Contractor is required to provide a nominated person(s) to attend the NJRSC and NJR sub-committees meetings. Attendance will be required at all relevant committee meetings and crucially, the NJR Editorial Board, NJR Research Committee and NJR Implant Scrutiny and Surgical Performance Committees.
- The Contractor is required to play an active role to support the committees by providing information required in a timely manner, ensuring that business development papers required for the NJRSC and NJR sub-committees are delivered within a set time and that relevant actions are taken forward and notified to the NJRMT.
- The Contractor is required to attend meetings as an observer with no voting right. At present the NJRSC and meets quarterly and the other NJR Sub-committees meet as outlined in section 2.2.3.

5.4.2. Contract delivery

The Contactor will take responsibility for the discharge and implementation of their appointed service provision for the delivery of the NJR programme including:

- Monthly statistics, management and service report
- Quarterly statistics reports relating to key outputs and KPIs
- Quarterly management and service reports relating to key outputs and KPIs
- The updating of a risk assessment register/log
- Development and updating of management strategy on a continuous basis including the NJR Strategic Plan and Annual Work Plan in liaison with and reporting to the NJR Director of Operations and NJRMT.

- The Contractor will appoint a Contract Manager with an appropriate level of expertise and with clear responsibilities and accountability, to oversee the work. This will include programme delivery, planning and reporting, and liaison with and reporting to a nominated member of the NJRMT and the NJRSC.
- The Contractor will appoint and retain appropriately skilled staff to deliver the services specified in this contract opportunity.
- The Contractor will perform quality assurance on all aspects of the programme detailed in this specification and ensure that quality assurance is evidenced during scoping, planning, initiation, testing and delivery phases of the programme.
- The Contractor will provide such reports and papers, via the NJRMT, to the NJRSC and NJR sub-committees and appointed working groups as requested and in a set time.
- The Contractor will attend such meetings and events as requested by the NJRMT and will provide technical assistance as required (e.g. system functionality demonstrations, presentations, explanations of analysis, attendance at conferences, workshops, events, distribution of NJR media). The Contractor is required to notify and seek approval from the NJRMT where invitations relating to the aforementioned activities are received directly.

5.4.3. Contract management

The Contractor is required to attend meetings to review progress and discuss the NJR, as required by the NJRMT as part of the contract delivery.

Contract management meetings will be held on an agreed basis to assess how the Contractor is satisfying the requirements of the Contract. The Contractor is required to provide supporting activity and service reports for each meeting in a format agreed with the NJRMT.

The agenda for each meeting will be set by the NJRMT and may include but is not limited to:

- A review of the Contractor's performance against the performance measures as perceived by the NJRMT
- Quarterly financial reporting against the submitted tender costs
- Performance issues requiring further action on the part of the NJRMT in terms of serving the Contractor with the required contractual notices
- Details of any remedial activities, to be undertaken by the Contractor during an agreed period

The following outcome-oriented criteria will be used for monitoring the Contractor:

- Adherence to any action plans agreed by both parties
- Performance reports are submitted on time, accurate, relevant and fully reflect the activities of the reporting period
- Transparency in invoicing and charges
- Satisfaction of NJRSC and other service users/stakeholders with the service(s) provided
- Responsiveness to actions and follow-ups approved by the NJRMT
- Overall consistency, quality and accuracy of the work produced

5.4.4. Relationships

- The Contractor will work effectively with the NJRMT and the appointed NJR statistical analysis, solutions and associated services Contractor.

- The contractor will hold regular minuted meetings with the appointed NJR statistical analysis, solutions and associated services Contractor to ensure smooth delivery of contracted work activities, issue identification and resolutions on an ongoing basis. Copies of minutes will be provided to the NJRMT within 10 working days of the meeting.
- The Contractor will attend six-monthly NJR Contractor meetings with the NJRMT and the appointed NJR statistical analysis, solutions and associated services Contractor
- The Contractor will work proactively and effectively with the NJRMT, NJRSC, NJR sub-committees and the NJR Patient Network to deliver the strategic goals and to work with any other contractors appointed by HQIP for the NJR programme.
- The Contractor will build effective relationships with stakeholders to help the NJR achieve its objectives - principally surgeons, NHS and independent (private) healthcare organisations, hospital managers and staff involved in the NJR process, Clinical Commissioning Groups, implant manufacturers/suppliers and representative groups (Association of British Healthcare Industries), Medicines and Healthcare products Regulatory Agency, patients (including the NJR Patient Network), patient representatives and organisations, National Institute for Health and Care Excellence, Care Quality Commission and other national and international agencies/groups (including Getting It Right First Time and Beyond Compliance), as directed by the NJRMT.
- The Contractor will effectively manage working arrangements with any sub-contractors who will be providing an additional services or other support as part of the total NJR data management, solutions and associated services provision. The Contractor will be responsible for managing any sub-contracting arrangements and maintaining excellent communication between all parties.
- The Contractor will co-ordinate both ongoing work and the initiation of any proposed new project work or other development activity under request of the relevant NJR sub-committee and direction and approval of the NJRMT.
- , ensuring timely reporting to the NJRMT on behalf of all contributors in delivery of common outputs.

5.5. Optional Associated Services

The contractor is invited to provide individual costing for the provision of the following services

- Routine collection of Patient-Reported Outcome Measures (PROMS) at a number of follow up points during the life of the contract
- Routine collection of Patient-Reported Experience Measures (PREMS)
- Project management and administrative services
- Annual Report Project Manager
    - The Contractor is invited to provide project management support to facilitate the production of the NJR Annual Report across all agreed formats (print, online, digital reports) working with the NJR Editorial Board, NJR statistical analysis, solutions and associated services Contractor, and NJRMT, taking direction from the NJRMT lead for the NJR Editorial Board.
    - This project manager would be required to produce a plan for the report content and publication timeline, including the collation of all sections for inclusion in the NJR Annual Report which can be found at www.njrreports.org.uk.
    - The activity of assembling of contents of the sections (currently known as Part One, Two, Four and appendices) and for those for the Online Annual Report will be delegated to the NJR Annual Report Project Manager (who will collate the collection of these documents from their authors and assemble them for initial discussion and

review, before being presented to the NJR Editorial Board for their review and approval.
    - This service will be reviewed on an annual basis. The minimum service duration is set at 12 months, and NJR can terminate this additional service at any point thereafter, subject to a minimum six- month notice period.
- Provision of general administration support – members' expenses
    - The Contractor is invited to provide general administration support for the processing of NJR Committee members' expenses (including travel expenses) as required prior to payment by NJR.
    - This service will be reviewed on an annual basis. The minimum service duration would be 12 months, and NJR can terminate this additional service at any point thereafter, subject to a minimum six-month notice period.
    - The Contractor will provide costs for these administrative services as an optional cost in the ITT breakdown.

6. Exit strategy

- The Contractor will provide a professional exit strategy to facilitate and enable the efficient transition of services at the termination or expiry of the contracts.
- The Contractor will provide full co-operation in supporting the managed and seamless transfer of services with minimal disruption of the service to the users.
- The transfer strategy will, where appropriate, support the transfer of infrastructure belonging to HQIP, and will allow all reasonable activity and access to support such a transfer.
- The exit strategy will include the development of an exit management plan. Which will include activities, timescales, and dependencies necessary to affect a smooth, planned, transfer of services this will include interaction with new suppliers.

7. Service levels and Key Performance Indicators (KPIs)

Granular level KPI for deliverables are outlined with the detailed specification and will be agreed with the Contractor before the start of the contract.

Overarching KPIs for delivery include

a. Data quality - Data will meet required standards and validity. Data will always be comparable, complete and accurate.
- Data should be checked for accuracy and error rates with alerts if errors exceed acceptable levels
- Quantitative measures of data completeness, consistency, integrity and timeliness should be consistently met
- Data should be cleaned and prepared against the agreed master format/methodology
- Data quality improvement work should be routinely performed and should be quantifiable (e.g. number of data issues found and corrected per month/quarter)
- Data should be consistent and reconcilable across applications and processes,

b. Data management performance
- The level of performance expected is for the consistent and continual availability of data, reports and timeliness of delivery to source of request i.e. within specified turn-around time

- Data should be available to users and applications no matter when, where and how needed

c. System reliability

- The Contractor should deliver Integrity and availability of IT information, reporting, collection and database systems. To be maintained at all times (24/7), measured against number of outages, any breaches of network capacity to meet NJRs requirements, number of incidents and security standards maintained,
- All data relevant to NJR applications should be accessible regardless of source, structure, or format
- Data integrity should be maintained when moved/transferred across different/multiple systems

d. Adherence to data management standards and processes

- Information governance mechanisms should be built into data pipeline, processing platforms and data management system to enable adherence and compliance with governance rules regarding data collection, storage, distribution, data access rights and security controls i.e. access is secure and limited appropriately

e. Auditability of data

- Information flows, audit trails, documentation, cleansing methodology and data linkage should all be clearly documented

f. Support

- Service support should be consistently available, i.e. resolution time, service desk – first call resolution, customer satisfaction, contacts database up to date, and availability of user support.

8. General Data Protection Regulation (GDPR) and Data Protection Impact Assessments (DPIA)

- HQIP is the Data Controller and the Contractor is the Data Processor in respect of any Personal Data processed under this Contract.
- The Contractor shall take reasonable steps to ensure it is familiar with the Data Protection Legislation and any obligations it may have under such Data Protection Legislation, and shall at all times process all Personal Data and confidential personal information in accordance with Data Protection Legislation
- The Contractor shall at all times ensure that any Processing of Personal Data and/or confidential personal information shall take place only in accordance with the Contract and Data Protection Legislation. Any information obtained in confidence will also be subject to the common law duty of confidentiality.
- Where appropriate, the Contractor will screen data for non-consented patients treated in English hospitals in line with the recommendations of the national data opt out programme.
- The Contractor shall provide all reasonable assistance to the NJRMT in the preparation of any Data Protection Impact Assessment prior to commencing any processing. Such assistance may include:
    - a systematic description of the envisaged processing operations and the purpose of the processing
    - an assessment of the necessity and proportionality of the processing operations in relation to the services
    - an assessment of the risks to the rights and freedoms of data subjects

- the measures envisaged to address the risks, including safeguards, security measures and mechanisms to ensure the protection of Personal Data.

- The Contractor will ensure that they maintain a Data Protection and Security Toolkit (DSPT) with an adequate score for the duration of the Contract.

9. CONTRACT PERIOD

This contract will be let on an initial 36 month contract with an option to extend it by up to a further 24 months