Statistical analysis, 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 statistical analysis, 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 an NJR data Management, data solutions 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 statistical analysis and solutions services. The document also provides information on a set of optional associated services.

The associated services are a set of are optional services that relate to the delivery of other elements of the NJR statistical analysis 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.

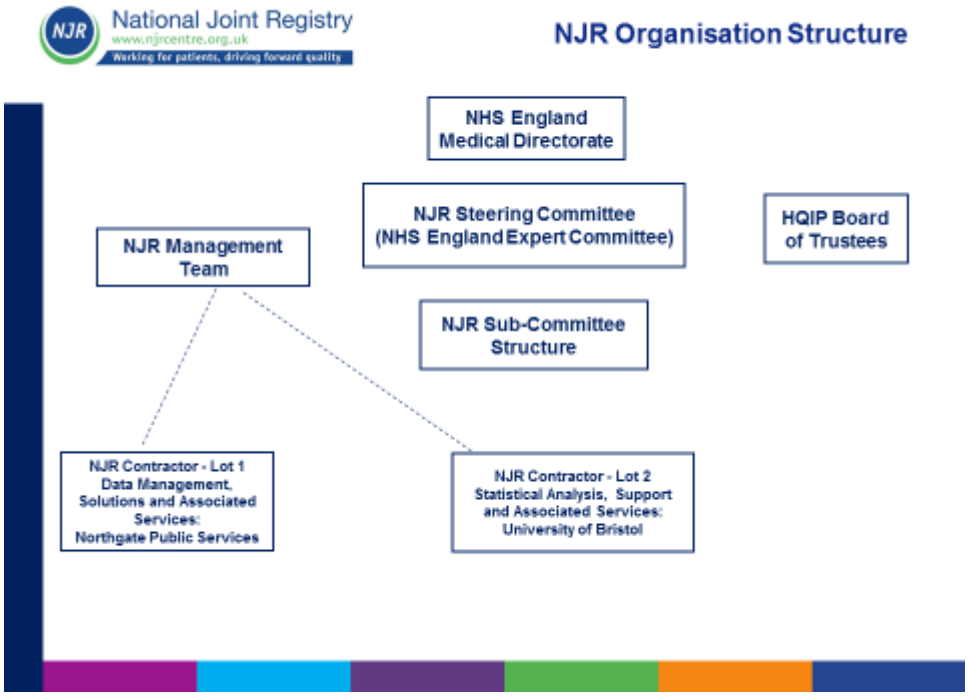
The Strategic Plan and Annual Work Plan are agreed and owned by the NJRSC.

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.

HQIP hosts the NJR Management Team (NJRMT) and acts as authority for NJR Contracts as well as assuming data controller responsibility (jointly with NHS England).

HQIP is the joint data controller with NHS England for the NJR. The Contractor for the NJR statistical analysis, support and associated services is a data processor alongside the NJR data management, solutions and associated services Contractor. Both contractors process personal data, but only the latter 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 ISC 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 ISC 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. 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 Benefits 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 NJR statistical analysis, solutions and associated services Contract (as outlined in section 0).

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. Statistical services, 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.

The NJR is committed to a coordinated programme of high quality data analysis and research that is disseminated widely and effectively in support of this vision. To achieve this, the NJR requires an intelligence function applying sound statistical skills, academic rigour and clinical experience to provide intelligent analysis and interpretation of the data for a wide variety of stakeholders.

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:

- Analysis of standard datasets including implant, hospital and surgeon outcome measures for the NJR Annual Report and ongoing stakeholder information services
- Development and maintenance of a robust statistical methodology for outlier identification and review of data validation
- Preparation of an annual research-ready dataset
- Targeted auditing of data quality
- Analysis of ad hoc datasets under instruction from NJRMT and sub-committees
- Reporting of findings and any limitations of the analysis
- Improvement of quality of datasets through data management and data cleaning processes.
- Provision of datasets to the benefit of the wider research community at the request of relevant 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.

- 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 is 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 database	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 Ankles Procedures entered on NJR in period	520	4,728
Total No. of Elbows Procedures entered on NJR in period	687	4,717
Total No. of Shoulders Procedures	3,902	38,362
Total Procedures last full year 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 % (Yes and No)	90.70%	94.50%
Valid Patient National Identifier %	95.20%	97.50%
% procedures entered into NJR with patient consent and NHS number i.e. (linkable)	68.10%	79.00%

- **Table 2: Key activity relevant to this Contract**

	March 2016 – April 2021	
Number of annual reports published	17 reports published to date	
Number of peer reviewed publications published	100	
	From outlier history 2020b i.e. Sept 2020	
Number of surgeon outliers detected	**Hips (5 and 10 years)**	**Knees (5 and 10 years)**
	230	271
Number of unit outliers detected	**Hips (5 and 10 years)**	**Knees (5 and 10 years)**
	113	145
Number of implant outliers detected (Level 1 and 2)		
Stems	88	
Cups	48	
Stemcups	169	
metal liners	8	
knees	52	
knee with patella	13	
knee without patella	17	
knee with/without patella	30	

4.2. Description of service

The scope of service to be delivered is for the Contractor to maintain and develop the statistical analysis, reporting and research functions 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:

- Statistical analyses of NJR data alongside data from other sources.
- Preparation of an annual research-ready dataset
- Analysis of standard datasets including implant, hospital and surgeon outcome measures for the NJR Annual Report and ongoing stakeholder information services
- Development and maintenance of a robust statistical methodology for outlier identification and review of data validation
- Preparation of an annual research-ready dataset
- Targeted auditing of data quality
- Analysis of ad hoc datasets under instruction from NJRMT and sub-committees
- Reporting of findings and any limitations of the analysis
- Provide technical support and input for ongoing gradual development and implementation of periodic revises to component database classifications for all joints
- Improvement of quality of datasets through data management and data cleaning processes.
- Provision of datasets to the benefit of the wider research community at the request of relevant NJR sub-committees

4.3. Immediate strategic priorities of the service

- Collection of patient-reported metrics remains a major priority for the NJR and the contractor will work with a multidisciplinary group – consisting of clinicians, academics, information management specialists and patient representatives implement to ensure that NJR develops its approach to collection and reporting of Patient Reported Outcome Measures (PROMs).
- Augmentation of the current potential outlier performance reporting to include shoulder, elbow, and ankle outcomes (subject to data quality – see section 0)
- Development and review of the minimum dataset and of associated data collection and reporting systems.
- Improvement of quality of datasets through data management and data cleaning processes
- Immediate implementation of Kaplan Meier and PTIR outlier detection methodologies
- Implement 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 data management, solutions and associated services contractor who have the responsibility for data collection and delivery of the data that the Contractor will use for its analyses. The Contractor will be required to maintain an ongoing collaborative and professional working relationship with the NJR data management, solutions and associated services Contractor to agree data cleaning and format, resolve issues of data quality and work on relevant NJR development activities
- The Contractor is required to work very closely with the NJR Editorial Board to participate in the planning and editorial cycle for publication of the NJR Annual Report as well as provide the statistical analysis and reporting required.

5. Detailed Requirements

5.1. Background

5.1.1. Specification summary

Provide statistical support to the NJR. Specifically to perform outlier analysis, produce agreed content for the NJR Annual Report, respond to ad hoc data requests and conduct an agreed research programme.

5.2. Scope

5.2.1. Analysis of standard datasets

5.2.1.1. Annual report

- The Contractor will provide a detailed statistical summary and commentary of the orthopaedic procedure activity over the previous year for the NJR Annual Report together with a detailed analysis of a range of outcome measures including implant survival relating to 5 and 10 year periods. Where appropriate this analysis will involve linkage of data between the NJR and other national data resources including, but not limited to, Health Episode Statistics (HES) and national and NJR-delivered Patient Reported Outcome Measures (PROMs).
- The content and scope of the NJR Annual Report is determined by the NJR Editorial Board and may vary and may require changes from year to year, requiring the Contractor to confirm its capability, and flexibility of resource, expertise and systems to provide the analysis and reporting required for any new analyses or presentations of data or any alterations to previously delivered analyses outlined by the Editorial Board.
- An essential requirement is that the Contractor works closely with all parties, keeping the NJR Editorial Board and NJRMT informed of any issues as they arise to ensure that the analyses and interpretation of data is presented in a timely manner in advance of NJR Editorial Board meetings
- The NJR Annual Report must be completed to a high standard to a strictly determined advance deadline (currently in the first week of July of each calendar year).
- Alongside the main annual report, the Contractor will also produce supplementary materials as directed by the NJR Editorial Board. This will include, but is not limited to, an appendix detailing the full use of implants in primary and revision surgery over the previous year; and expanded risk tables with annual time points for all survival analyses charts produced.
- The Contractor will apply appropriate disclosure control including the suppression of small numbers in all tabulated data, including those embedded in graphical figures (eg risk tables). Current best practice (see https://www.ons.gov.uk/methodology/methodologytopicsandstatisticalconcepts/disclosurecontrol/healthstatistics) is suppression of numbers in the range 1-3.
- As directed by the NJR Editorial Board, the Contractor will introduce new analyses of additional outcome measures on an ongoing basis. This is likely to include PROMs (from national PROMs data) and PREMS, non-revision reoperations (including but not exclusively limited to dislocation, peri prosthetic fracture fixation, conversion to fusion, excision, manipulation under anaesthetic, amputation) and other post-operative complications
- The NJR anticipates significant development of the NJR Annual Report analysis of implant survivorship at construct and component level to expand to include multiple joints. This will include work to classify constructs used in shoulder, elbow and ankle surgery, hip hemiarthroplasty and endoprostheses used in tumour surgery.

- The Contractor is invited to outline the mechanism by which they would routinely capture, exploit and integrate HES data into NJR reporting to provide analysis of additional outcome measures the NJR seeks to understand and report on. The Contractor will be expected to start with an exploration of cases with a diagnosis code associated with periprosthetic fractures.
- The Contractor will work with the NJRMT, NJR Editorial Board and NJR data Management, data solutions and associated services Contractor to develop interactive, public-facing online charts and tables to be made available via the NJR Online Annual Report website.

Key outputs:

- Data preparation at an agreed frequency, currently March for the purposes of the Annual Report within an agreed timeframe from receipt of data
- Instigate analysis and reporting within one calendar month from data receipt
- Production of analysis, charts, tables and commentary for inclusion in the NJR Annual Report within an agreed timeframe
- Provide summary reports of any in-depth studies approved within an agreed timeframe
- Under the direction of the relevant NJR sub-committees and the NJRMT assist with the content of high quality research papers for publication in academic journals

5.2.1.2. Outlier analysis

- The Contractor will provide a detailed analysis of a range of outcome measures including implant survival relating to 5 and 10 year periods. Where appropriate this analysis will involve linkage of data between the NJR and other national data resources including, but not limited to, Health Episode Statistics (HES) and national and NJR-delivered Patient Reported Outcome Measures (PROMs).
- The NJR requires the Contractor to develop mechanisms for reporting on an expanding range of joint replacement survivorship types and reasons for failure and will include exploiting and cultivating analysis of a range of additional outcomes and end points including pre and post-operative PROMS and linked Patient Reported Experience Measures (PREMs). Timescale for reporting will be advised and agreed by the NJR at the start of the contract. Reporting of these end points will be scaled up across the term of the contract
- There is scope to augment the current performance reporting to include shoulder, elbow, and ankle outcomes. This expansion will take place over time during the contract starting initially with shoulders reporting at hospital unit level. The expectation is that reporting of the additional joints will be staggered to include shoulders in year one, ankles by year 3 and elbows by year 4. This will depend on the quality and completeness of data and should be provided as a variant cost (see section 0)
- Implant outlier analysis should be conducted using both a Kaplan Meier methodology and a Patient Time Incidence Rates (PTIR) methodology from the commencement of the contract. Surgeon and unit level outliers will use a risk-adjusted standardised mortality ratio (SMR) and risk-adjusted standardised revision ratio (SRR). The Implant Scrutiny Committee may direct that one of the analyses variants may be discontinued during the contract term.

- As directed by the Surgical Performance and Implant Scrutiny Committees, the Contractor will introduce new analyses of additional outcome measures on an ongoing basis. This is likely to include PROMs (from national PROMs data), and PREMS, non-revision reoperations (including but not exclusively limited to dislocation, peri prosthetic fracture fixation, conversion to fusion, excision, manipulation under anaesthetic, amputation) and other post-operative complications
- Hospital unit level analysis will be extended to also report at NHS Trust (England), Health Board (Wales), Health and Social Care Trust (Northern Ireland), Integrated Care System footprint (England), Independent sector group, revision network, formal and informal groupings of hospitals and other levels of aggregation as directed by the Surgical Performance Committee.
- The Contractor will introduce up to one new sub-stratification of implant performance reporting per joint per cycle (i.e. every six months) for example reporting on all cruciate retaining and posterior stabilised knees as separate strata. The scope of this activity will be directed by the Implant Scrutiny Committee.

5.2.1.3. Statistical methodology for outlier identification and review of data validation

The NJR currently identifies outlier data for implants, surgeons and units using an NJRSC-approved methodology. This leads to a clearly defined process for managing and reporting verified implant, surgeon and unit potential outliers which is constantly monitored and developed.
This is an important area of work and one in which the NJR aims to use the most up to date, best validated and most robust statistical methodology.

- The NJR statistical analysis, support and associated services Contractor will be required to undertake regular and ad hoc investigation and reporting of potential outliers as requested by and in accordance with the requirements of the Surgical Performance Committee and Implant Scrutiny Committee.
- The Contractor will advance, refine and develop the current NJR methodology for continuous monitoring of outliers to ensure relevant risk factors influencing performance are taken into account in outlier detection.
- In applying and developing these methods for outlier detection, the Contractor will work closely with the NJRSC and its Surgeon Performance and Implant Scrutiny Committees to ensure this process is both on-going and rigorous.
- The Contractor will ensure that new stratifications of the data are introduced into the routine analysis on instruction of the committees to support signal detection.
- All methodology should be fully transparent. Detailed technical descriptions should be made available detailing data cleansing, tests used, adjustment co-efficient and other relevant technical detail. A plain English summary should also be made available for publication.

Key outputs:

- Immediate implementation of current outlier detection methodology to include both Kaplan Meier and PTIR methods for implant analysis
- Agreed timetable for discussion of the refinement of case mix adjustment
- Regular reporting of outlier analysis along timelines determined by the Surgeon Performance and Implant Scrutiny Committees and data capture, currently March and

August/September

- Ad hoc investigation and reporting of potential outliers in accordance with the requirements of the Surgeon Performance and Implant Scrutiny Committees

5.2.1.4. Quality of datasets, data management and data cleaning processes

- The Contractor is required to constantly monitor the quality of the datasets passed to them by the NJR data management, solutions and associated services Contractor using quality indicators agreed with the NJRMT.
- The Contractor will provide a detailed specification to the NJR data management, solutions and associated services Contractor in advance of all data releases and confirm following data release that data is in line with that specified.
- The Contractor is also required to regularly document and report on the quality of data against agreed quality indicators to an agreed timetable. The Contractor will be working closely with the relevant NJR sub-committees and will meet periodically with the NJRMT to determine the validity of the rules and measures used to ensure data quality and shall support the implementation of any required alterations.
- The Contractor will notify the NJRMT immediately of any instance where data does not match after cleaning has taken place and work directly with the NJR data management, solutions and associated services contractor to resolve any inaccuracies or differences within the data
- The Contractor will work closely with the NJR data management, solutions and associated services contractor to reduce duplication of cleaning steps and maintain a consistent approach to reporting (see section 5.2.3)
- The Contractor will work collaboratively and constructively with NJR data management, solutions and associated services contractor to agree the final dataset which will be the main source for all data outputs and published data including onward sharing of the dataset.

5.2.1.5. Production of data to support stakeholders

The Contractor will be required to supply extracts of analysed data to key stakeholders to support strategic and operational activity across orthopaedic services. This will include, but is not limited to:

- Supply of outcomes data to support the NJR Clinical Outcomes Programme
- Supply of outcomes data to support Care Quality Commission dashboards and the National Clinical Audit Benchmarking service
- Supply of outcomes data to support Getting it Right First Time and Model Hospital
- Ad hoc analyses and supply of data to support investigations by the Medicines and Healthcare products Regulatory Authority

Data specification and level of aggregation will be agreed with the NJRMT for each release, but is likely to include reporting of activity and outcomes data at hospital unit, NHS Trust (England), Health Board (Wales), Health and Social Care Trust (Northern Ireland), Integrated Care System footprint (England), Independent sector group, revision network, formal and informal groupings of hospitals.

5.2.2. Research programme

5.2.2.1. NJR research programme

The Contractor is required to undertake a programme of research and analysis on a number of individual topics in association with and set by the NJR Research Committee, with approval and direction of the NJR Executive Committee.

- The scope and associated deliverables required for these topics will be agreed annually with the Contractor. The topics will be set at pre-advised NJR Research Committee meetings, at which appointed representatives of the Contractor will be expected to attend
- Projects that form part of this annual NJR research programme, will require NJR Research Committee application and quarterly updates to the NJR Research Committee will be required as part of the contract monitoring processes. Any variations to the agreed research programme must be formally requested in writing to the NJR Research Committee.
- Nominated members of the NJRSC or Research Committee will be assigned as NJR leads for research programme projects. These members must be included in a meaningful way in project design, conduct, analysis and reporting.
- Applications for research projects using NJR data that do not form part of the NJR annual research programme, will only be considered where NJR funded resources are not involved in the study.

Key outputs:

- Delivery of required research against an annual programme of research topics

- Produce an annual in-depth Topic proposal summary for submission to the pre-advised NJR Research Committee detailing all proposed in-depth topics on which the Contractor will be taking a leading role on using NJR data during the following year. This should include:
  a) topic areas
  b) specific research questions
  c) intended outputs
  d) anticipated milestones

5.2.2.2. Health economics

- The NJR anticipates harnessing health economics tools to review, analyse and evaluate the benefits of NJR data and service delivery. It is intended to establish the cost effectiveness of uses of NJR data to improve services and of surgical and other clinical choices in the delivery of joint replacement surgery.
- The contractor is invited to outline its vision of how it would expand the use of health economics tools to assist this agenda.

5.2.2.3. Production of research-ready data

- The Contractor is required to provide a cleaned and annotated, research-ready dataset on an annual basis for third parties to be able to conduct analysis on data equivalent to that used for core NJR outputs.

Key outputs:

- Produce on request a research-ready dataset within each calendar year that is suitable for statistical and epidemiological analysis based on the data provided by the NJR data management, solutions and associates services contractor within an agreed timeframe
- To provide the research-ready data in a format and quality that is suitable to be accessible on the NJR Data Access Portal.

5.2.2.4. NJR fellows

The NJR, in partnership with the Royal College of Surgeons, runs an academic fellowship programme for two fellows over a period of two years at any one time. This is part of the NJR strategy to maximise the value of the data held in the database. The Fellows are supported by their academic institution and responsible to the NJR Research Committee and NJRMT. As part of the fellows' induction, and under instruction of the Chair of the Research Committee, the Contractor is required to provide advice and assistance, as necessary, to support the fellows. This will involve supporting them in navigating and understanding the data in the pursuance of their NJR Research Committee approved studies to ensure robustness of analysis and quality in outputs.

5.2.3. 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 interpretations of the different 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 data management, solutions 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 within the first six months of the contract. A specification for this activity will be provided by the NJRMT.
- The Contractor will be required to provide and maintain an outline of the methodology used, in particular data cleansing steps, to ensure methodology can be replicated and outputs reproduced. This should be provided in both technical language, including details of all inclusions, exclusions, adjustment co-efficients and other relevant technical detail and in plain English. The NJR will publish this information to maximise transparency.
- The Contractor will provide and continually update a template of the methodology applied to data provided by the NJR data management, solutions and associated services contractor for other organisations

5.2.4. Targeted auditing of data quality

- Under the direction of the NJR, the Contractor and the Data Quality Committee will undertake ad hoc audit activity of NJR data focussing on specific procedures, implants, units or other elements to ensure the quality of data within the NJR dataset.
- The Contractor will be required to report any findings of interest, contribute to investigations (where appropriate) into the underlying causes of any issues identified, and propose issue resolution measures.

Key outputs:

- Provide guidance to the NJR Data Quality Committee and the NJRMT on how to sample and conduct ad hoc audits on the quality, accuracy and completeness of the NJR data
- Provide analysis and reporting as required for such ad hoc audits
- Production of a data quality issues log which should consist of information such as data quality issues and risks identified which will be fed back to the NJR data management solutions and associated services Contractor to action where appropriate.

5.2.5. Intellectual property

- HQIP owns and will continue to own the analysis code for all analyses conducted in the context of this contract including, the NJR Annual Report, outlier analysis and research conducted as part of the NJR research programme.

5.2.6. 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 provision of a detailed dataset specification for each data release required by the Contractor.
    - The timely production and release of an annual update to the data cleansing methodology to the NJR data management, solutions and associated services Contractor
    - The timely production and delivery of the annual research ready dataset

- Performance of the Contractor shall be measured on but not limited to the following criteria:
    - Delivery of potential outlier reports within an agreed timescale of receipt of datasets from the NJR data management, solutions and associated services Contractor
    - Delivery of other standardised periodic reports, within an agreed timescale, following receipt of datasets from the NJR data management, solutions and associated services Contractor
    - Delivery of the annual research-ready dataset for the Data Access Portal
    - Delivery of analysed datasets and commentary for the NJR Annual Report as directed by the NJRMT and the Editorial Board
    - Delivery of ad hoc analysis to the timeframe agreed for each piece of analysis
    - Assistance with publication of results in a timely and professional manner
    - Demonstrable progress with projects under the NJR research programme to the satisfaction of the NJR Research Committee

- 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.

5.3. General requirements

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

5.3.1. 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.

5.3.2. 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 activity and service report relating to key outputs and KPIs
- Quarterly activity and service report relating to key outputs and KPIs
- The updating of a risk assessment register/log as appropriate and directed by the NJRMT
- 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. This person should be suitably qualified in project or programme management and have adequate, ring-fenced, non-academic/clinical time available for management of the Contract.
- The Contractor will appoint and retain appropriately skilled staff to deliver the services detailed in this specification.
- The Contractor will perform quality assurance on all aspects of the programme detailed in this specification.
- The Contractor will provide such reports and papers, via the NJRMT, to the NJRSC and NJR sub-committees and 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 statistical support assistance as required (e.g. presentations, demonstrations, explanations of analysis, attendance at conferences, events, distribution of NJR media).
- Travel and subsistence expenses should be included in your cost breakdown. The Contractor is required to notify and seek approval from the NJRMT where invitations relating to the aforementioned activities are received directly.

5.3.3. 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

5.3.4. Relationships

- The Contractor will work effectively with the NJRMT and the appointed NJR data management, solutions and associated services Contractor.
- The contractor will hold regular minuted meetings with the appointed NJR data management, 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 data management, 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 statistical or other support mechanism as part of the total NJR statistical analysis, 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 direction of the relevant NJR sub-committee, ensuring timely reporting to the NJRMT on behalf of all contributors in delivery of common outputs.

5.3.5. Brand Guidelines

The contractor will need to adhere to and consult with the NJRMT for any further advice or clarification on NJR brand guidelines, and ensure that guidelines are circulated and adhered to on all NJR project work by all Contractor's staff.

5.4. Optional associated services

Due to the potential for the volumes of data or data quality being insufficient, the Contractor should provide as a breakdown cost delivery of the provision of shoulder, elbow and ankle joint outcomes for reporting in the NJR Annual Report and outlier analysis outputs.

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 Contract.
- 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 transfer strategy will where appropriate support the transfer of data under the controllership of 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 KPIs for deliverables are outlined with the detailed specification and will be agreed with the Contractor before the start of the Contract. Overarching broad KPIs for delivery include

a) Delivery of potential outlier reports across all joints within an agreed timescale of receipt of dataset(s) from the NJR data management solutions and associated services Contractor
b) Delivery of other standardised periodic reports within an agreed timescale following receipt of dataset(s) from the NJR data management, solutions and associated service Contractor
c) Delivery of analysed datasets and commentary for the NJR Annual Report within specified timescales
d) Delivery of ad hoc analysis to the time frame agreed for each piece of analysis
e) Documentation, review and distribution of the data cleaning methodology, standard and the format in which data is to be received to the by the NJR data management, solutions and associated services Contractor in line with agreed frequency and timeline.
f) Reporting on the quality of data against an agreed methodology to an agreed timetable.
g) All outputs in line with contractual obligations and NJR priorities and Strategic Plan
h) Statistical outputs for outlier analysis consistent with those for the NJR Annual Report

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.
- 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 39 month contract with an option to extend it by up to a further 24 months