National Joint Registry
www.njrcentre.org.uk

National Joint Registry Supplier Feedback

Terms of Use

This document constitutes the "Terms of Use" referred to in the Supplier Feedback 2 Services - Terms and Conditions ("Terms and Conditions"), part of the Supplier's contract with HQIP for the Services. . Capitalised terms used in these Terms of Use which are not defined herein are as defined in the Terms and Conditions.

The access to and use of the Services by the Supplier and Authorised Users is granted subject to the Supplier complying with the terms of the Licence and compliance with these Terms of Use. The National Joint Registry ("NJR") is the team that provides the Services at HQIP.

The National Joint Registry Steering Committee ("NJRSC") recognises that the orthopaedic industry, as a key stakeholder, has a number of statutory obligations under the Medical Device Regulations. The NJRSC has therefore accepted the principle of Suppliers having access to the Healthcare Quality Improvement Partnerships (the "Authority") data on their products for post market surveillance ("PMS") purposes under the Terms and Conditions and these Terms of Use.

Principles of Data Access

1. Authority data allows Suppliers to undertake internal analysis integrated with other PMS signals to help identify any emerging performance trends, particularly for newly introduced products, with the aim of identifying possible issues before implants reach possible outlier status.

2. Suppliers of orthopaedic devices are granted access to the Authority data through the Services for the exclusive purpose of conducting PMS of their own product portfolio, to monitor the safe and appropriate use of these products.

3. Suppliers may obtain data from the Services on their own product portfolio except in those situations where:
    - surgeons have implanted off-label product combinations (mix & match) in which case each affected supplier will receive details of all implants used;
    - bone cement is used in the arthroplasty, in which case the implant companies receive details of the cement used.

    Manufacturers of bone cement may not receive details of implants unless the company markets both the cement and the implant.

4. HQIP provides access to pseudonymised patient, surgeon or unit level data. If data is required in a more identifiable format, it is only available through submission of a data request to the NJR.

5. The dataset supplied using the Services is summarised in Appendix 1.

Conditions of Data Use

6. The Services are provided subject to compliance with the Terms and Conditions.

7. Permitted third parties are as set out in Appendix 3.

Implant Summary Reporting Service

8. Notwithstanding any restrictions set out in the Terms and Conditions or herein, if Supplier subscribes to the NJR Implant Summary Reporting Service, the Supplier is permitted to distribute the Implant Summary Report generated via such service (in its entirety only) for

any purpose deemed appropriate by the Supplier, at any time prior to and including the "valid until date" applicable to such report. After the "valid until date" the Supplier is not permitted to further distribute, copy or reproduce the NJR Implant Summary Report(s).

9. In addition, the Supplier may publish a NJR Implant Summary Report in whole or in part, provided that:

- where published in part form, such publication clearly references the NJR Implant Summary Report from which any extract has been taken;
- where published in part form, the Supplier makes the entire NJR Implant Summary Report publicly available (such as through a public website) for review;
- no claim or representation is made on behalf of HQIP; and
- any publication must contain the NJR Disclaimer (Appendix 2).

Post Market Surveillance (PMS) Reporting Service

10. Notwithstanding section 8 above, if a Supplier subscribes to the NJR Implant Summary Reporting Service, the Supplier shall be granted access to PMS reports for their registered NJR brands. These reports are restricted for internal Supplier use only and must not be released to any third party without prior written permission of the Authority, with the exception of submissions to global regulatory authorities and notified bodies, as detailed in Appendix 3.

Hospital Profile Reporting Service

11. Notwithstanding any restrictions set out in the Terms and Conditions or herein, , if a Supplier subscribes to the Hospital Profile Reporting Service, the following additional conditions of use apply:

The Supplier agrees and acknowledges that the release of surgical unit identities with matching NJR unit numbers is subject to the Supplier complying with the Terms and Conditions and these Terms of Use and any other obligations made known to the Supplier. The Supplier shall not share such data outside of its organisation e.g. with other suppliers, the media, or otherwise place this data in the public domain.

- The Supplier agrees that any data on a surgical unit performance:

  a. May only be used for internal and regulatory purposes and may not be distributed or otherwise published to any third party whatsoever.

  b. Identifiable unit-specific data may only be shared with that surgical unit and its management, and any other data must be properly anonymised.

- The Supplier may use the NJR surgical unit data combined with its own internal records and information to decide how best to approach the surgeon(s) at a particular surgical unit when further information is needed.

- Suspected surgical unit or surgeon outlier performance issues together with appropriate data may be referred, in strict confidence, to the NJR Surgeon Performance Committee by the Supplier for further investigation where the Supplier considers this necessary.

Bespoke Reporting Service

16. Notwithstanding any restrictions set out in the Terms and Conditions or herein, HQIP may provide bespoke reporting services to Suppliers. Specific report requests may be produced with or without onward distribution licensing terms. Bespoke reports will clearly define what the licensing term is within the reports themselves, as deemed by the Authority. The following conditions of use apply:

- Reports produced with onward distribution licensing terms follow the same terms of use as the Implant Summary Reporting Service, as set out above in points 8 and 9.

- Reports produced without onward distribution licensing terms follow the same terms of use as the Post Market Surveillance (PMS) Reporting Service, as set out above in point 10

"Specially Collected Data"

15. From time to time, the Supplier may commission HQIP to collect additional PROMs data from patients receiving the Supplier's implants ("Patient Follow-up / PROMs Service"). Through this service, HQIP shall deliver a bespoke patient PROMs Service for the collation and secure feedback of anonymised PROMs data from a defined patient cohort. Data collected through this service shall be classified as "Specially Collected Data".

16. Specially Collected Data shall be subject to the Terms and Conditions and these Terms of Use, save and except:

- it shall not be eligible for release to external third parties without the express permission of HQIP.

- it may, on agreement of HQIP, be retained by the commissioning organisation, independent of ongoing subscription to the Services.

Use of "Specially Collected Data"

17. Use of Specially Collected Data within research or publication of reports using Specially Collected Data within peer-reviewed journals is subject to approval by the NJR Research Committee (NJRRC). Such requests should be directed through the NJR research request process at:

http://www.njrcentre.org.uk/njrcentre/Research/Research-requests

Appendix 1

NJR Supplier Feedback Dataset

Data on Primary and Revision Arthroplasty

Specific NJR Data fields under each heading are supplied as relevant to primary or revision arthroplasty surgery and may be adjusted in line with any changes made to the MDS.

1. Primary NJR patient/ case identifiers
2. Primary MDS number
3. Patient demographics (e.g. age, gender, BMI, ASA grade, side, indication for surgery)
4. Date of surgery
5. Primary surgical unit and surgeon identifier numbers
6. Primary procedure type and approach
7. Primary product construct implant and cement details (e.g. manufacturer, brand, component code, description, batch number, etc)
8. End point type (unrevised, dead, revised)
9. End point date
10. Observed years to end point
11. Age at death
12. Revision NJR patient/ case identifiers
13. Revision date
14. Revision reasons
15. Revision surgical unit and surgeon identifier numbers
16. Revision procedure type
17. Components removed
18. Revision product construct implant and cement details (e.g. manufacturer, brand, component code, description, batch number, etc)
19. Revision MDS number

Appendix 2

NJR Disclaimer

The data used for this analysis was obtained from the National Joint Registry ("NJR"), part of the Healthcare Quality Improvement Partnership (“HQIP”). HQIP, the NJR and/or its contractor, Northgate Public Services (UK) Limited ("NPS") take no responsibility (except as prohibited by law) for the accuracy, currency, reliability and correctness of any data used or referred to in this report, nor for the accuracy, currency, reliability and correctness of links or references to other information sources and disclaims all warranties in relation to such data, links and references to the maximum extent permitted by legislation including any duty of care to third party readers of the data analysis.

Appendix 3

a) Approved Global Regulatory Authorities for Sharing Reports / NJR Supplier Feedback datasets, or analysis undertaken upon these datasets

Country	Name	Country	Name
America (US)	Food & Drug Administration	**Japan**	Ministry of Health, Labour and Welfare
Australia	Therapeutic Goods Administration	**Japan**	Pharmaceuticals and Medical Devices Agency
Austria	Austrian Agency for Health and Food Safety	**Latvia**	State Agency of Medicines
Belgium	Federal Agency for Medicines and Health Products	**Liechtenstein**	Office of Health / Department of Pharmaceuticals
Bulgaria	Bulgarian Drug Agency	**Lithuania**	State Medicines Control Agency
Croatia	Agency for medicinal products and medical devices of Croatia	**Luxembourg**	Ministry of Health
Cyprus	Ministry of Health - Pharmaceutical Services	**Malta**	Medicines Authority
Czech Republic	State Institute for Drug Control	**Netherlands**	Medicines Evaluation Board
Denmark	Danish Medicines Agency	**Netherlands**	Healthcare Inspectorate
Estonia	State Agency of Medicines	**Norway**	Norwegian Medicines Agency
Finland	Finnish Medicines Agency	**Poland**	Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
France	National Agency for the Safety of Medicine and Health Products	**Poland**	Chief Pharmaceutical Inspectorate
Germany	Federal Institute for Drugs and Medical Devices	**Portugal**	National Authority of Medicines and Health Products
Germany	Paul Ehrlich Institute	**Romania**	National Medicines Agency
Greece	National Organization for Medicines	**Slovakia**	State Institute for Drug Control
Hungary	National Institute of Pharmacy and Nutrition	**Slovenia**	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia
Iceland	Icelandic Medicines Agency	**Spain**	Spanish Agency for Medicines and Health Products
Ireland	Health Products Regulatory Authority (HPRA)	**Sweden**	Medical Products Agency
Italy	Italian Medicines Agency	**United Kingdom**	Medicines and Healthcare Products Regulatory Agency

b) Approved Notified Bodies for Sharing Reports / NJR Supplier Feedback datasets, or analysis undertaken upon these datasets

Country	Name	Country	Name
Austria	TÜV AUSTRIA SERVICES GMBH	**Italy**	ITALCERT SRL
Belgium	SGS Belgium NV	**Italy**	KIWA CERMET ITALIA S.P.A.
Czech Republic	ELEKTROTECHNICKÝ ZKUŠEBNÍ ÚSTAV, s.p.	**Italy**	Eurofins Product Testing Italy S.r.l.
Czech Republic	INSTITUT PRO TESTOVÁNI A CERTIFIKACI, a. s.	**Netherlands**	DEKRA Certification B.V.
Denmark	Presafe Denmark A/S	**Norway**	DNV GL Nemko Presafe AS
Finland	VTT Expert Services Oy	**Poland**	POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.
Finland	SGS FIMKO OY	**Poland**	DQS Polska Sp. z o.o
France	Laboratoire national de métrologie et d'essais / G-MED	**Slovakia**	3EC International a.s.
Germany	TÜV NORD CERT GmbH	**Slovenia**	SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - SIQ
Germany	TÜV SÜD Product Service GmbH Zertifizierstellen	**Spain**	AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS
Germany	DEKRA Certification GmbH	**Sweden**	RISE Research Institutes of Sweden AB
Germany	TÜV Rheinland LGA Products GmbH	**Sweden**	INTERTEK SEMKO AB
Germany	DQS Medizinprodukte GmbH	**Switzerland (MRA)**	SCHWEIZERISCHE VEREINIGUNG FÜR QUALITÄTS- UND MANAGEMENTSYSTEME
Germany	ecm-Zertifizierungsgesellschaft für Medizinprodukte in Europa mbH	**Switzerland (MRA)**	QS Zürich AG
Germany	MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN GMBH	**Turkey**	TURKISH STANDARDS INSTITUTION (TSE)
Germany	MDC MEDICAL DEVICE CERTIFICATION GMBH	**Turkey**	Kiwa Belgelendirme Hizmetleri A.Ş.
Greece	NATIONAL EVALUATION CENTER OF QUALITY AND TECHNOLOGY IN HEALTH S.A.-EKAPTY	**Turkey**	Szutest Uygunluk Değerlendirme A.Ş.
Hungary	Országos Gógyszerészeti és Élelmezés-egészségügyi Intézet Eszközminősítő és Kórháztechnikai Igazgatóság (National Institute of Pharmacy and Nutrition)	**Turkey**	UDEM Uluslararasi Belgelendirme Denetim Egitim Merkezi Sanayi ve Ticaret Limited Sirketi
Hungary	CE Certiso Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.	**United Kingdom**	BSI
Ireland	National Standards Authority of Ireland (NSAI)	**United Kingdom**	LLOYD'S REGISTER QUALITY ASSURANCE LTD
Italy	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	**United Kingdom**	SGS United Kingdom Limited
Italy	IRCM ISTITUTO DI RICERCHE E COLLAUDI MASINI S.R.L.	**United Kingdom**	AMTAC CERTIFICATION SERVICES LTD