SERVICE LEVEL AGREEMENT FOR 2017 to 2019

made between

1. NHS ENGLAND

and

2. United Kingdom Haemophilia Centre Doctors' Organisation Ltd

SERVICE LEVEL AGREEMENT

CONTENTS

DEFINITIONS

In these Conditions, unless the context otherwise requires:

"Trusts"	means all Provider Trusts within England
"Commissioners"	means nominated commissioners within NHS England
"Start Date"	means 1st April 2017
"End Date"	means 31st March 2019
"Commissioner"	NHS England
"Nominated Representatives"	means the nominated representatives of "Commissioner" and "Provider"
"Parties"	means both NHS England "Commissioner" and United Kingdom Centre Doctors' Organisation Ltd "Provider"
"Provider"	means United Kingdom Centre Doctors' Organisation Ltd which hosts the National Haemophilia Database
"Service"	means the provision of all aspects of the "SLA" including data validation and reporting requirements as set out in section 2
"SLA"	means the agreement concluded between the "Parties" which includes all the sections to be read as one document comprising ; Section 1 Section 2 Section 3
"Trusts"	Means all trusts in England who are required to submit data to the NHD

THIS SERVICE LEVEL AGREEMENT is made

BETWEEN:

(1) United Kingdom Haemophilia Centre Doctors' Organisation Ltd, C/O Secretariat, UKHCDO, City View House, Union Street, Manchester, M12 4JD (the "Provider")

and

(2) NHS England London, Skipton House, 80 London Road, London, SE1 6LH (the "Commissioner")

in respect of the "Services" that will be provided by the National Haemophilia Database (NHD).

The "SLA" "Start Date" is 1st April 2017 and "End Date" is 31st March 2019.

By signing off this "SLA" no precedent for the future funding levels shall be set.

Nominated "Commissioner" Representative	Andrew Goodman, Regional Director of Specialised Commissioning (London) Richard Jeffery Head of Financial Management [redacted]
Nominated "Provider" Representative	Prof. Charles Hay Director, UKHCDO Ltd

(together "Nominated Representatives")

The "Provider" and "Commissioner" have agreed to this "SLA".

Signed for and on behalf of the "Provider" by its nominated representative:

..... GRO-C
(print name)

Signed ..... GRO-C 22.8.17

Signed for and on behalf of the "Provider" by its nominated representative:

GRO-C

(A Goodman)

Signed for and on behalf of the "Commissioner" by its nominated nominated representative:

R Jeffery.....
(print name)

Signed .... GRO-C .....

Signed ... GRO-C

SECTION ONE – SERVICE LEVEL AGREEMENT

"SLA" made between

NHS England

and

United Kingdom Haemophilia Centres Doctors' Organisation (UKHCDO) Ltd as host of the National Haemophilia Database (NHD)

The NHD is a database managed by UKHCDO Ltd. It holds identifiable data on individuals with haemophilia and other bleeding disorders. Submission of information to the NHD by all trusts is mandatory, however, individuals may opt out of identifiable data being held on them.

This "SLA" is made between the UKHCDO Ltd, the organisation responsible for managing the NHD and NHS England "Commissioner" for haemophilia services. This contract is on behalf of NHS England and as detailed in Appendix 1.

1. **The "Provider" will provide the following services to the "Commissioner":**
   - Provision of data collection from "Trusts", forms and procedure manuals and relevant updates.
   - Reports on data submitted by "Trusts" as detailed in the dataset in Section 2 of the "SLA".
   - The production of ad-hoc reports and data in response to specific requests from the "Commissioner" to be discussed and, where reasonable and agreed, between the "Parties".
   - Monitoring and quarterly reporting on usage of blood factors replacement therapies and related products subject to national framework agreements.

- The collection and collation of other data, by the NHD, agreed between the UKHCDO and commissioners to support commissioning activities including data to demonstrate benchmarking of clinical outcomes and patient reported outcome measures both between providers and NHS England.
- Continued training of data collection methods with "Trusts" in Haemophilia Centres
- Provision of bespoke data collection software to "Trusts".
- Provision of administrative and technical support via telephone, email and visits as required
- Invitation to any relevant UKHCDO or NHD meetings, training or events.
- Evidence of Information Governance compliance.

Services provided by the "Provider" must comply with the following:

- All data provided by the "Provider" will conform to the Data Protection Act (1998) and amendments and NHS Caldicott Guardian requirements in relation to confidentiality as set out in the document 'Confidentiality NHS Code of Practice' (Nov 2003) and standards as detailed in the Information Governance Toolkit.
- Patient access to data will conform to the Freedom of Information Act (2000).
- All communications between the "Provider" and "Trusts" containing identifiable patient data must be sent and received by secure nhs.net email.
- A full breakdown of costs included in the total funding request.

2. **The responsibilities of the "Commissioner" are:**

- The continuous involvement of the "Commissioner" in the development of the NHD dataset through a range of measures including being a representative on the UKHCDO Data Management Working Party, and a member of any other groups that may be established to support development of the dataset.
- Ad hoc communication with the UKHCDO National Haemophilia Database Manager or nominated representative.
- To be represented on the UKHCDO Data Management Working Party with "All Trusts" clinicians represented through being members of the UKHCDO.
- To agree the total funding under the terms of a Service Level Agreement on behalf of NHS England as set out in section 3.
- The "Commissioner" will ensure the timely submission of accurate data from "Trusts" in accordance with the data collection schedule for:
    - Collection of quarterly data, by the last day of the month following the end of the quarter
    - Notification of: Patient registrations, de-registrations and amendments to registrations, within 1 month of the event occurring
    - Notification of adverse events: Development of an inhibitor, Allergic event, fatal event, Intracranial Haemorrhage, Infectious event, Malignant or neoplastic event, Poor Efficacy event or Thrombotic event, and other adverse events as deemed clinically relevant, within two weeks of the event
- Quarterly, to review performance against the agreed KPIs for the relevant period.

TERMS AND CONDITIONS

1. COMMENCEMENT AND TERM

1.1 This "SLA" shall commence on the "Start Date" and cover the defined and agreed months.

1.2 This "SLA" shall continue for a period of 24 consecutive months. Thereafter the "SLA" may be extended which shall be agreed by the "Commissioner" for a term of not less than 12 months, and dependent upon availability of "Commissioners" agreeing to make provision for funding and on the performance of the "SLA" against the agreed terms and conditions and dataset and reporting requirements as set out in Section 2. The "Commissioner" shall notify the "Provider" of the decision to continue the "SLA" on before the "End Date" of the current "SLA".

2. CONDUCT OF THE "SLA"

2.1 The "Provider" shall use its reasonable endeavours to carry out the "Service" and terms and conditions of this "SLA". The "Provider" will deliver all reporting requirements as set out in Section 2 on time. Failure to do this may result in non-payment, or a reduction in payment.

2.2 Either of the "Parties" may change the identity of the "Nominated Representatives" by giving written notice to the other party.

2.3 The day to day data collection, data validation and analysis under the "Service" shall be managed by the "Provider".

2.4 Any failure of "Trusts" to return accurate quarterly data to the NHD by the agreed dates should be referred to the "Commissioner" or the "Nominated Representative", who will endeavour to assist and remedy.

3. FINANCIAL PROVISIONS

The UKHCDO shall invoice NHS England who shall pay all monies due to the "Provider" and in the manner and on the times as specified in Section 3 for services that have been provided in line with the agreed KPIs

4. REPORTING AND INFORMATION ACCESS AND USE

4.1 The "Provider" will submit reports to the "Commissioner" together with an Annual Report to be submitted to identified recipients in NHS England, the Public Health Network, Department of Health etc. covering the previous financial year within the dates set out in Section 2.

4.2 The "Provider" undertakes to provide the "Commissioner" with ad hoc data requests which the "Commissioner" may reasonably require to enable the analysis of and planning for the provision of services. For complex requests the "Provider" may charge the "Commissioner" an additional cost which should be agreed between the two parties prior to the commencement

of work being undertaken by the "Provider"

4.3 NHS England, The Public Health Network and Department of Health shall use the data provided by the "Provider" to support analysis, reporting and planning healthcare services.

5. CONFIDENTIALITY AND DATA STORAGE

5.1 Collection, handling and use of data relating to individuals shall be treated as confidential at all times by the "Provider", who is responsible for ensuring that all identifiable data received from "Trusts" is used and stored in a way that meets the Data Protection Act (1998) and amendments and NHS Caldicott requirements and the Freedom of Information Act (FOI) 2000.

5.2 The "Provider" should undergo an inspection every two years to demonstrate compliance to the satisfaction of the Caldicott Guardian. The draft report should be circulated to the "Commissioner" and any other NHD commissioners.

5.3 The "Provider" commits to review and update the dataset at least once per annum to ensure that all data captured is still required and will report on all data protection measures taken within the Annual Report of the "Provider".

5.4 The "Provider" will ensure that individuals, whose identifiable data is stored, are made aware of their rights in relation to the data. A number of measures to be provided by the "Provider" shall include: patient leaflets (which require annual review) to be distributed to Haemophilia Centres to ensure as wide a range of patients as possible receive them; "Provider" website to hold dataset and reasons for holding identifiable data.

5.5 The "Provider" agrees to provide the "Commissioner" with their published Data Quality document and any revisions as necessary and to provide evidence of Data Quality Accreditation in line with this document.

5.6 All reports and data provided to the "Commissioner" will ensure that where small numbers of data may enable the identification of an individual, that these are reflected in a way that will prevent this from occurring.

5.7 NHS England (the "commissioner"), the Public Health Network and Department of Health may manipulate data provided to support their work and can disclose any data obtained from the "Provider" to other stakeholders as appropriate.

5.8 The "Provider" shall at all times be responsible for ensuring that all data, including data stored in electronic format, is stored securely and shall take appropriate measures to ensure the security of such data and guard against unauthorised access.

6. LIABILITY

6.1 The "Provider" will endeavour to ensure the accuracy of its work through application of data validation processes. The "Commissioner" acknowledges that provision of data to the "Provider" is not mandatory for individuals and that individuals may opt out of agreeing for

their details to be submitted to the NHD therefore potential gaps in data may arise and where this occurs, the "Provider" will highlight this in all reporting as set out in Section 2.

6.2 The "Commissioner" takes all data supplied by the "Provider" at its own risk and agrees to indemnify the "Provider" against any claims, costs or expenses that arise from the "Commissioner" or other nominated parties using the data.

7. TERMINATION

7.1 This "SLA" may be immediately terminated by the "Commissioner" if:

7.2 The "Provider" shall have a receiver or administrator appointed, should go into liquidation, or be unable to provide the "Service".

7.3 This "SLA" may be immediately terminated by the "Provider" if:

7.4 NHS England fails to make payment exactly in accordance with Section 3.

7.5 This "SLA" may be immediately terminated by either "Parties" if the other party shall be in material breach of this "SLA" and following written notice of such breach by the other party fails to remedy such breach within 28 days.

7.6 This "SLA" may be terminated by either "Parties" by providing the other party with 6 months notice in writing.

7.7 For the avoidance of doubt (except where termination is through the material breach of the "Commissioner" under clause 7.4) if the "SLA" is terminated (without prejudice to its general rights at law) the "commissioners" shall be entitled to at least recover from the "Provider" payment equal to the amount of financial commitment already entered into by the "commissioners" at the date of termination.

8. GENERAL

8.1 This "SLA" constitutes the entire agreement and understanding between the "Parties" relating to the "Service" and supersedes all other representations, promises and understandings.

8.2 All notices and agreements required to be given pursuant to this "SLA" shall be to the "Nominated Representatives" of the "Parties" either by (a) facsimile and by confirming letter sent by first class mail posted within 48 hours of the said facsimile or (b) mail by first class recorded delivery post. In proving posting, it shall be sufficient to produce the relevant post office receipt for despatch by recorded delivery.

8.3 Neither "Parties" to this "SLA" shall be liable to the other nor held to be in breach of this "SLA" to the extent that it is prevented, hindered or delayed in the performance or observance of its obligations (other than the payment of any funding due hereunder) by reason of industrial action, strikes, lock-outs, inability to obtain supplies, accidents or any other cause beyond its control.

8.4 Any provision of this "SLA" which in any way contravenes the applicable law shall be deemed severable and shall not invalidate any other provision or provisions of this "SLA".

8.5 No variation to this "SLA" may be made by any person unless agreed in writing between the "Nominated Representatives".

8.6 This "SLA" shall be governed and interpreted by the laws of England, NHS policy and guidance and any data protection laws and acts including the Data Protection Act (1998) and amendments.

SECTION TWO – DATA SET AND REPORTING REQUIREMENTS

The "Provider" agrees to capture the published National Haemophilia Database data set and will discuss with the "Commissioner" any additions or deletions to the dataset. Where any "Trusts" do not submit data to the NHD due to data protection concerns, the "Provider" will take all endeavours to address these to enable a full dataset to be collected.

2.1 DATASET REQUIREMENTS

The "Provider" agrees to use the dataset to develop the range of reports as set out in clause 2.2.

2.2 REPORTING REQUIREMENTS

Information will be available to the Area Teams/Regions, Public Health Network and Department of Health as follows

Real-time reporting, accessible via website, available to "Commissioners" by CCG, Trust, Sub-region ('hub') and Region
• Notification of new inhibitors
• Adverse events
• New registrations (GP Practice code included)
• Notification of deaths and causes thereof

N.B. Real-time reporting will become available once the organisational structures are clarified and the service has been redeveloped to take account of this.

The "Provider" agrees to make available, electronically or as hard copy, all reporting as detailed below to NHS England Regional specialised commissioning teams, Public Health Network and Department of Health:

Specific Data Reporting requirements	**Date(s) for Data to be available of the relevant year**	**Frequency M = monthly Q = quarterly A = annually**
Monitoring of factor usage to support National Framework Agreements for clotting factors and related products	Aug Nov Feb May	Q
UKHCDO Annual Report for each financial year	31st October	A

Other data reports and benchmarking reports	Date(s) for Data to be available	Frequency M = monthly Q = quarterly A = annually
Benchmark patient profile and epidemiological data across, for Severe Haemophilia A and Severe Haemophilia B • CCG • Trusts • Sub-region ('hub') • Regions and the UK (e.g. age; type of bleeding disorder; clotting factor use). Benchmarking of clotting factor usage should be against, for Severe Haemophilia A and Severe Haemophilia B • CCG • Trusts • Sub-region ('hub') • Regions. Trusts and Regions and sub-regions must be identifiable and not anonymised.	31st October	A
Benchmark clotting factor product usage for each year from 2007/08 up to the present time by quarter, identifying increases / decreases in product usage. The benchmarking usage against • Trusts • Sub-regions ('hub') • Regions Trusts and Area Teams/Regions must be identifiable and not anonymised. N.B. Real-time reporting will become available once the organisational structures are clarified and the service has been redeveloped to take account of this.	At end of following quarter i.e. Q1 by end Aug Q2 by end Nov Q3 by end Feb Q4 by end May	Q

Other data reports and benchmarking reports	Date(s) for Data to be available, of the relevant year	Frequency M = monthly Q = quarterly A = annually
Benchmark usage, product type, unit price, costs and suppliers across all patients with all bleeding disorder conditions across • CCG • Trusts • Specialised Commissioning Hubs • Regions and UK Identifying increases / decreases in product usage. The benchmarking usage against other Hubs/Regions must be identifiable and not anonymised.	31st October	A
Breakdown and report current inhibitors by Trust and Hubs/Regions N.B. Real-time reporting will become available once the organisational structures are clarified and the service has been redeveloped to take account of this.	31st October	A
Report newly registered patients in "Trusts"	31st October	A
Benchmark clinical outcomes nationally, according to the measures and populations agreed by the CRG or Data Management Working Party.	30th April	A
Benchmark patient reported outcomes (PROMs) nationally, according to the measures and populations agreed at the CRG or Data Management Working Party.	30th April	A

N.B. Any additional benchmarking opportunities should be discussed with the "Commissioner" prior to the development of tools or monitoring methods that may not be of interest to commissioners.

2.3 ACTIONS TO BE TAKEN IN THE EVENT OF FAILED DELIVERY

In the event of non-delivery of reports NHS England will in the first instance instigate performance management measures and revised deadlines, if these are also not met then payment will be withheld in line with Section 3.

2.4 KPIs for PERFORMANCE MANAGEMENT

KPI	RESPONSIBILITY		ACTION if KPI not met
	PROVIDER	TRUSTS	
REPORTING			
Real time reporting of • Notification of new inhibitors • Adverse events • New registrations • Notification of Deaths and causes thereof	Processing of information submitted by "Trusts" in accordance with section 1 part 2	Timely notification from "Trusts" in accordance with section 1 part 2	Performance notice. Funding withheld in line with section 3.1 breakdown if no improvement. Penalty payment by trusts
Quarterly reporting of rFVIII usage against the national contract	Processing of information from NHD and the Commercial Medicines Unit (CMU)	Accurate and timely Quarterly data returned from all "Trusts"	Performance notice. Escalation to DH if non delivery. Funding withheld in line with section 3.1 breakdown
Benchmarking and annual review of data in the Annual Report including Clinical Outcome monitoring and Patient reported outcomes	Processing of information and production of reports	Accurate and timely submission of data	Performance notice Funding withheld for non-delivery in line with section 3.1 breakdown Penalty payment by trusts
INFORMATION			
Review of patient leaflet with extensive distribution of any updated information	Review, update, publish and circulate patient leaflet		Performance notice Funding withheld for non-delivery
Updated information available on the website	Review and update all information		Performance notice Funding withheld for non-delivery
Compliance with information governance	Compliance with all aspects of IG including data quality accreditation and Caldicott Guardian review		Performance notice. Action plan to be developed in the event of any breech compliance with all aspects

KPI	RESPONSIBILITY		ACTION if KPI not met
	PROVIDER	TRUSTS	
REPORTING			
OTHER			
Support for "trusts" with provision of data collection, forms, procedure manuals and training in data collection			Performance notice. Action plan to be developed for compliance with all aspects
Patient registration card to be released for distribution by all "Trusts"	Release of new patient registration card		Performance notice Funding withheld for non-delivery

Request for Data

It is expected that should commissioners request it, the entire data set held by UKHCDO Ltd should be made available to them, within the limit of patient consent and our obligation to maintain DPA principles.

SECTION THREE – FUNDING AND PAYMENT

Invoices should only comprise costs directly related to the provision of service for the National Haemophilia Database. Software development and maintenance must be restricted to charges relating to the NHD. Any development charges must be agreed with the "Commissioner" prior to the development work being undertaken through discussion and agreement of the annual work plan with the "Commissioner". The development and maintenance of other software applications must be funded separately.

It is expected that costs will be calculated in line with NHS costing principles.

3.1. Breakdown of funding for service:

UKHCDO will:

Provide a breakdown of costs to support the value of the requested payment for NHS England.

The total value of the contract 2017/18 is [redacted] (+ VAT) = [redacted]

The total value of the contract for 2018/19 is [redacted] (+ VAT) = [redacted]

3.2 Ad Hoc Reports

Ad hoc requests are included in the contract and will be delivered within a timely manner where agreed with the lead commissioner for the Specialised Blood Disorders CRG.

3.3 Payment Schedule

NHS England to be invoiced annually at the end of the first quarter.

Invoice reference:

XXAGO

Invoice Addresses:
NHS England
X24 Payables K005
London Specialised Commissioning
Phoenix House, Topcliffe Lane
Wakefield,
West Yorkshire WF3 1WE
XXJBEGUM

"Provider" Registered Charity Number: 1032606