Medicines and Healthcare products Regulatory Agency (MHRA) Patient Safety Monitoring, Safety and Surveillance

Services Agreement between:

Secretary of State for Health and Social Care acting through the Medicines and Healthcare products Regulatory Agency as part of the Crown

and

The Newcastle upon Tyne Hospitals NHS Foundation Trust

For

Yellow Card scheme promotion and education work

This Agreement is made on the date of the parties' signatures below

BETWEEN

The Secretary of State for Health acting through the Medicines and Healthcare products Regulatory Agency, whose main office is situated at 10 South Colonnade, Canary Wharf, London E14 4PU (**MHRA**);

AND

The Newcastle upon Tyne Hospitals NHS Foundation Trust, whose main office is situated at Freeman Hospital Freeman Road, High Heaton, Newcastle upon Tyne NE7 7DN (the **Provider**).

(each a Party and collectively referred to in this Agreement as the Parties).

WHEREAS:

(A) This Agreement sets out the terms between the Provider and MHRA under which the Provider will carry out promotional and educational activities in respect of the Yellow Card scheme.

(B) The Yellow Card scheme is the voluntary reporting scheme by which healthcare professionals and members of the public report suspected adverse drug reactions to the MHRA.

IT IS AGREED AS FOLLOWS:

1 Definitions

1.1 In this Agreement the following words and expressions shall have the following meanings unless the context requires otherwise:

ADR	Suspected Adverse Drug Reaction (ADR) to a medicine (includes vaccines or herbal products) commonly referred to as side effects, incidents, adverse incidents, or adverse events, adverse reactions, events to medicinal products
'Aggregated'	Combined data from two or more reports of one or more incidents reported or submitted to the MHRA
Annual Report	Means the report prepared annually by the Provider as described in Annex 5

Business Day	means a day, other than a Saturday, Sunday or public holiday in England, when banks in London are open for business.
Business Hours	the period from 9.00 am to 5.00 pm on any Business Day.
Charges	Being the amount payable by to MHRA to the Provider in accordance with Clause 8.
Commencement Date	1 April 2023
'Competitor' or 'Competing Business'	Means one that operates, in any capacity, in the pharmaceutical industry, pharmacovigilance and other spontaneous reporting systems for the collection of suspected ADRs problems associated with medicinal products in the United Kingdom
'Confidential Information'	means any information, however it is conveyed, that relates to the business, affairs, developments, trade secrets, Know-How, personnel and suppliers of the MHRA or the Provider, including IPRs, together with information derived from the above, and any other information clearly designated as being confidential (whether or not it is marked as "confidential") or which ought reasonably to be considered to be confidential, including, without limitation all Non-Aggregated data received by the Provider from the MHRA in respect of this Agreement particularly data which includes Personal Data
'Controller', 'Processor', 'Data Subject', 'Personal Data', 'Special Categories of Personal Data', 'processing' and 'appropriate technical and organisational measures'	shall have the meanings given to them in the Data Protection Legislation.

'Data Protection Legislation'	Means all applicable data protection and privacy legislation in force from time to time in the UK including the UK GDPR; the Data Protection Act 2018 (DPA 2018); and the Privacy and Electronic Communications Regulations 2003 (SI 2003 No. 2426) as amended; and any other legislation and regulatory requirements in force from time to time which apply to a Party in relation to privacy and the protection of personal data, which may include the EU GDPR.
'Deliverables'	means any outputs of the Services and any other documents, products and materials provided by the Provider to the MHRA as specified in Annex 1 and any other documents, products and materials provided by the Provider to the MHRA in relation to the Services
'Disclosing Party'	the Party directly or indirectly providing Confidential Information to the other Party in accordance with Clause 18 18 (Confidentiality)
'Electronic Data'	Shall include but not be limited to offline electronic storage and information retrieval systems of a digital, optical or magnetic nature including floppy disk, CD-ROM, CD-I, DVD, ROM-card, compact disc, video, USB devices, external digital storage, integrated circuit: mobile and handheld devices; online transmission by satellite and other means of telecommunication; and any other electronic means of reproduction, publication, dissemination and transmission whether now in existence or hereafter invented
EU GDPR	Means the General Data Protection Regulation ((EU) 2016/679).
Existing IPR	any and all Intellectual Property Rights that are owned by or licensed to either Party and which have been developed independently of the Agreement (whether prior to the date of the Agreement or otherwise);
Extended Term	has the meaning set out in clause 2.1
FOIA	Means the Freedom of Information Act 2000, and any subordinate legislation made under the Act from time to time,

	together with any guidance and/or codes of practice issued by the Information Commissioner or relevant government department in relation to such legislation.
Information Commissioner	the Information Commissioner as defined in section 3(8) of the DPA 2018.
Initial Term	has the meaning set out in clause 2.1
'Intellectual Property Rights'	Means: (a) copyright, rights related to or affording protection similar to copyright, rights in databases, patents and rights in inventions, semi-conductor topography rights, trade marks, rights in internet domain names and website addresses and other rights in trade or business names, goodwill, designs, Know-How, trade secrets and other rights in Confidential Information; (b) applications for registration, and the right to apply for registration, for any of the rights listed at (a) that are capable of being registered in any country or jurisdiction; and (c) all other rights having equivalent or similar effect in any country or jurisdiction;
'Law'	any law, subordinate legislation within the meaning of Section 21(1) of the Interpretation Act 1978, bye-law, right within the meaning of the European Union (Withdrawal) Act 2018 as amended by European Union (Withdrawal Agreement) Act 2020, regulation, order, regulatory policy, mandatory guidance or code of practice, judgment of a relevant court of law, or directives or requirements of any regulatory body with which the Provider is bound to comply
Medical Device Incident	The term 'medical device' covers a broad range of products that are used in healthcare. They can be physical items or software which are used for the diagnosis, prevention, monitoring or treatment of illness or disability. Products reportable to the Yellow Card scheme as a medical device will have a CE or UKCA mark. An adverse incident is an event that caused, or almost

	caused, an injury to a patient or other person, or a wrong or delayed diagnosis and treatment of a patient
Medicinal product	Healthcare products regulated by the Medicines and Healthcare products Regulatory Agency to ensure safe and effective use such as medicines, traditional herbal remedies and complimentary products, vaccines, blood products, e-cigarettes, medical devices, defective or falsified (fake) products.
New IPR	all and Intellectual Property Rights in any materials created or developed by or on behalf of the Supplier pursuant to the Agreement but shall not include the Supplier's Existing IPR;
New IPR Items	means a deliverable, document, product or other item within which New IPR subsists;
'Non-Aggregated'	Data from a single report of one or more ADRs or medical device incidents submitted to the MHRA
Open Licence	means any material that is published for use, with rights to access and modify, by any person for free, under a generally recognised open licence including Open Government Licence as set out at http://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/ and the Open Standards Principles documented at https://www.gov.uk/government/publications/open-standards-principles/open-standards-principles;
'Personal Data Breach'	Means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to the Shared Data
'Provider Staff'	all directors, officers, employees, agents, consultants and contractors of the Provider and/or of any subcontractor engaged in the performance of the Provider's obligations under the Agreement
'Recipient Party'	the Party which receives or obtains directly or indirectly Confidential Information

Services or Objectives	Means the activities outlined in Annex 1
Shared Data	Means the Personal Data shared by the Data Owner with the Data Recipient pursuant to this Agreement, as further described in Annex 8.
Third Party IPR	intellectual property rights owned by a third party which is or will be used by the Provider for the purpose of providing the Deliverables.
UK GDPR	Has the meaning given to it in section 3(10) (as supplemented by section 205(4)) of the Data Protection Act 2018.
Working Day	a day (other than a Saturday or Sunday) on which banks are open for business in the City of London.
'Yellow Card Centres' (YCCs) (YCC in the singular)	The Provider acting through the department or business unit within the Provider delivering the Services.
'Yellow Card Data'	Data taken directly from reports of one or more adverse drug reactions and safety problems such as those associated with other healthcare products such as e-cigarettes, medical device incidents, defective or falsified (fake) products through the Yellow Card scheme or patient safety related events submitted to the MHRA. Yellow Card Data are the property of the Secretary of State for Health
Yellow Card scheme	means the pharmacovigilance system known by the same name which enables the collection of information on adverse drug reactions, operated by the MHRA in relation to its powers and duties in Part 11 of the Human Medicines Regulations 2012/1916, acting as the licensing authority (as defined in regulation 6 thereof). This also includes the vigilance and reporting of other medicinal products such as medicines, vaccines, e-cigarettes, medical device incidents, defective or falsified (fake) products to

	the Medicines and Healthcare products Regulatory Agency to ensure safe and effective use.
Yellow Card Strategy	Work intended to grow, increase awareness and develop the Yellow Card scheme as more particularly described as having four themes in relation to improving reporting: Facilitation, Education, Motivation and Promotion of the scheme underpinned by partnerships and collaborations.
YCC Head	Being the person named in Annex 7 for the YCC

2 Agreement period/term

2.1 This agreement shall commence on the Commencement Date and shall continue, unless terminated earlier in accordance with clause 13 (Termination), until 31 March 2024 ("**Initial Term**"), when it shall terminate automatically without notice unless, no later than three months before the end of the Initial Term (or any Extended Term agreed under this clause), the parties agree in writing that the term of the agreement shall be extended for up to a maximum of four 12 month periods the Agreement to terminate no later than 31 March 2028 ("**Extended Term**"). Unless it is further extended under this clause or terminated earlier in accordance with clause 13 (Termination), the agreement shall terminate automatically without notice at the end of an Extended Term.

2.2 Any extension of the agreement is subject to the confirmation by MHRA and the completion of the review at the end of each year.

3 Services

3.1 The Provider shall:

3.1.1 provide the Services and the Deliverables in accordance with Annex 1;

3.1.2 ensure that the Services and Deliverables will conform in all respects with Annex 1 and that the Deliverables shall be fit for any purpose expressly or implicitly made known to the Provider by the MHRA;

3.1.3 perform the Services with the highest level of care, skill and diligence in accordance with best practice in the Provider's industry, profession or trade;

3.1.4 ensure that the Deliverables, and all materials, standards and techniques used in providing the Services are of the best quality and are free from defects in workmanship, installation and design;

3.1.5 co-operate with the MHRA in all matters relating to the Services, and comply with the MHRA's instructions;

3.1.6 before the date on which the Services are to start, obtain and at all times, maintain during the term of this agreement, all necessary licences and consents and comply with all applicable Laws in relation to the Services; and

3.1.7 In relation to the Provider's personnel, the Provider shall ensure that all personnel involved in the provision of the Services have suitable skills and experience to enable them to perform the tasks assigned to them, and that such personnel are in sufficient number to enable the Provider to fulfil its obligations under this agreement.

4 Performance management

4.1 The MHRA will assess the quality and service delivery of the Provider based on the following criteria:

4.1.1 The ability of the Provider to deliver the Services.

4.1.2 The Provider must send an annual report to the MHRA within three months of the last quarter's Yellow Card Data provided during each year from the MHRA, on promotional activities undertaken in the previous financial year, including dates, outlets, Yellow Card work produced and institutions visited. The format of the annual report is outlined in Annex 5. The format of the report is subject to change each year in agreement between both Parties or upon request to review/update.

4.2 The Provider may review and agree with the MHRA at the start of each year changes to the Services provided they are measurable, achievable, realistic and time-bound objectives and demonstrate how each have been met in its annual report.

5 Audit

5.1 The Provider shall allow the MHRA (or its professional advisers) to access the Provider's premises, personnel, systems and relevant records to verify that Yellow Card Data supplied by the MHRA to the Provider are being used and securely held in accordance with the terms of this Agreement.

5.2 Subject to the Provider's confidentiality obligations, the Provider shall provide the MHRA (and its professional advisers) with all reasonable co-operation, access and assistance in relation to each audit.

5.3 The MHRA shall provide at least one Business Day's notice of its intention to conduct an audit and any audit shall be conducted during Business Hours.

5.4 The MHRA and its professional advisers shall have the right to take copies of any records which they reasonably require and remove such copies and the Provider shall provide the necessary facilities to assist in copying free of charge.

6 Storage and destruction of data

6.1 The Provider shall ensure that each member of his staff engaged in the Services observes the conditions of this agreement and any further or supplementary Agreement, including variations, agreed by the Parties hereto and that such members of staff are advised of any changes to those conditions.

6.2 The Provider shall at all times ensure that storage of Yellow Card Data is secure and where this is Personal Data that this is secure in accordance with the obligations contained in the Data Protection Legislation. The Provider shall also ensure that each member of staff engaged in the Services maintains confidentiality in accordance with clause 18 18of this Agreement and shall undertake quarterly reviews of the need to retain such data.

6.3 All personal specific Yellow Card Data received by the Provider is confidential (defined as Confidential Information) and must be kept under lock and key when not under personal supervision. All Electronic Data must be kept securely in a password protected environment. The Provider must abide by the Guidelines for safe disposal of Electronic Yellow Card Data at Annex 3 and ensure that all employees who have access to the data also comply with this policy.

6.4 Individual Yellow Cards that are personal specific, if received by the Provider should be sent securely to the MHRA.

7 Data protection

7.1 The Parties shall comply with their respective obligations set out in Annex 8 of this Agreement.

8 Charges

8.1 The MHRA shall pay the Provider a contribution towards the costs incurred by the Provider in delivering the Services.

8.2 The Charges for financial year 2023/24 are: Redacted under FOIA Sect 43(2) Commercial Interests sum with no VAT added and no VAT should be added to the invoice).

8.3 Charges for any period of Extended Term will be subject to annual review and approval by the MHRA.

8.4 The MHRA may reimburse additional expenses subject to written approval by MHRA in advance of the expense being incurred.

8.5 The Parties will agree the cost of any additional services that may be agreed between the Parties.

8.6 Once the Charges have been paid, the Provider will be free to administer the funds within the terms of the agreement without further reference to the MHRA for service delivery.

8.7 Payment of the Charges will be made in in advance and at the beginning of each financial year, following receipt of an invoice from the Provider. The Provider shall include in the invoice all details reasonably requested by the MHRA, such as the purchase order number.

9 Varying the services to be provided

9.1 Amendments to this agreement can be made in writing with the agreement of both Parties where either Party makes proposals to add to, modify or remove part of the service described in this document.

9.2 Where the MHRA requests the Provider to carry out other vigilance related activities, both Parties shall agree the nature of those activities and any associated costs.

10 Communications

10.1 The Provider will be represented at an annual meeting with the MHRA, the YCC Head and members of their staff will be invited to attend. Meetings between the MHRA and YCC Heads will be held as required throughout the year and the MHRA will reimburse expenses incurred by the Providers' staff as a result of attending such meetings subject to advance agreement.

10.2 Each Provider's YCC will be represented at quarterly telephone conferences with the MHRA to discuss all aspects of Yellow Card work including future planned activities which will be coordinated through the MHRA and aligned with Yellow Card Strategy.

10.3 Aggregated data provided to the Provider by the MHRA for promotion, education and communication purposes can be shared externally in accordance with Annex 4.

10.4 Any other communication in which the Provider proposes to include Yellow Card Data shall be approved by the MHRA and should be submitted to the MHRA's liaison officer listed at Annex 2, in accordance with Annex 4. This includes any requests or aspects in relation to media or Parliamentary business.

10.5 Any requests for information under the FOIA received by the Provider in relation to this Agreement shall be referred to the MHRA. In case of any doubt, clarification should be sought.

10.6 No information which could reasonably lead to the identification of living individuals who are the subject of Yellow Card reports shall be included in any publications without the prior agreement in writing of those living individuals concerned and permission of the MHRA.

10.7 Any Provider Staff when acting in accordance with the provisions of this agreement should identify themselves as acting for and on behalf of the relevant YCC.

11 Parties' obligations

11.1 Under the terms of this Agreement, the Provider shall deliver the Services and co-operate with the MHRA in all matters related to the Services.

11.2 Under the terms of this Agreement, the MHRA will:

11.2.1 pay the Charges as they fall due;

11.2.2 contact the Provider's YCC to follow-up local initiatives and respond to queries within the Provider's region to facilitate local engagement with stakeholders to increase Yellow Card reporting.

11.2.3 respond to routine requests from the Provider in accordance with its seven working day target.

12 Accountability

12.1 The Provider will use its best endeavours to nominate a named individual(s) as the YCC Head who will be accountable to the MHRA as well as for the delivery of the Services set out in clause 3 4 and Annex 1. The Provider will agree any nomination for the post of YCC Head with the MHRA.

12.2 No waiver or delay in acting upon any of the requirements of this Agreement shall release either Party from performance of its remaining obligations in this Agreement.

12.3 Neither Party shall be liable to the other for any failure or delay in supplying or procuring to supply any materials, services or goods to the other under the terms of this Agreement due to circumstances beyond its reasonable control (including but not limited to any act of God, war, threatened war or terrorism or threatened terrorism, strike, lockout, industrial action, fire flood drought tempest - "Force Majeure Events") and it shall not be liable for any direct costs or expenses or consequential losses whatsoever suffered during the period of Force Majeure Events.

13 Termination

13.1 The MHRA may terminate this Agreement by giving not less than two months' written notice to the Provider.

13.2 Without affecting any other right or remedy available to it, either Party may terminate this Agreement with immediate effect by giving written notice to the other Party if the other party commits a material breach of any term of this agreement and (if such breach is remediable) fails to remedy that breach within a period of 60 days after being notified in writing to do so. Due consideration by the MHRA will be given to variables that may impact objective delivery.

13.3 Any provision of this Agreement that expressly or by implication is intended to come into or continue in force on or after termination or expiry of this agreement shall remain in full force and effect.

13.4 Termination or expiry of this agreement shall not affect any rights, remedies, obligations or liabilities of the Parties that have accrued up to the date of termination or expiry, including the right to claim damages in respect of any breach of the agreement which existed at or before the date of termination or expiry.

13.5 In the event of termination, the Provider must return any data or information to the MHRA or destroy such data as appropriate and agreed with the MHRA.

14 Dispute resolution

14.1 The Parties shall attempt to resolve any difference or dispute between them by negotiation in the first instance. Any difference or dispute between the Parties shall in the first instance be referred to nominated liaison officers for resolution. In the event that these officers are unable to resolve the dispute then it shall be referred to the next most senior level of management of both Parties.

15 Obeying the law

15.1 The Provider must, in connection with provision of the Deliverables:

15.1.1 comply with all applicable Laws relevant to the Services;

15.1.2 comply and procure that any subcontractors comply with the Supplier Code of Conduct: (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/779660/20190220-Supplier_Code_of_Conduct.pdf) as such Code of Conduct may be updated from time to time;

15.1.3 comply with the provisions of the Official Secrets Acts 1911 to 1989 and section 182 of the Finance Act 1989;

15.1.4 support the MHRA in fulfilling its Public Sector Equality duty under section 149 of the Equality Act 2010;

15.1.5 comply with the model Agreement terms contained in Example 1 of Annex C of the guidance to PPN 05/19 (Tackling Modern Slavery in Government Supply Chains) shall apply to the Agreement, as such clauses may be amended or updated from time to time; and

15.1.6 meet the applicable Government Buying Standards applicable to Deliverables which can be found online at: https://www.gov.uk/government/collections/sustainable-procurement-the-government-buying-standards-gbs.

16 Law and jurisdiction

16.1 A person who is not a Party to this Agreement has no right to enforce the benefit of any term of this Agreement and to the extent permitted by law the Parties hereby exclude the application of Contracts (Rights of Third Parties) Act 1999 to this Agreement.

16.2 Nothing contained in this Agreement shall in any way create any association, partnership or the relationship of principal and agent between the Parties hereto or be construed as evidencing the intention of the Parties to constitute such a relationship.

16.3 If a provision of this Agreement (or part of any provision) is found illegal, invalid or unenforceable, the provision shall apply with the minimum modification necessary to make it legal, valid and enforceable.

16.4 The MHRA and the Provider agree that this agreement is to be governed by and construed according to English law.

16.5 To the fullest extent permitted by law, the Parties acknowledge that this Agreement contains the whole Agreement between the Parties and supersedes all previous agreements whether express or implied.

17 Non-compete and conflicts of interest

17.1 The Provider will not engage in Competing Business, or with any other business that can in any way be deemed a Competitor of the Yellow Card scheme, during the Agreement, and for a period of two years after termination of the Agreement.

17.2 Specifically, YCCs may not, directly or indirectly, own, lease, control, operate, participate in, manage, provide services for, consult with, advise, or permit its name to be used by any business that competes with the Yellow Card scheme or is related to the pharmaceutical industry in any way; if so this must be disclosed by the Provider immediately. It is understood that staff who might be engaged in the Services or involved with the YCC may also be involved in bona fide research and any conflicts of interest should be managed appropriately by the Provider and declared to the MHRA as relevant.

18 Confidentiality

18.1 Each Party must:

18.1.1 keep all Confidential Information it receives confidential and secure;

18.1.2 not disclose, use or exploit the Disclosing Party's Confidential Information without the Disclosing Party's prior written consent, except for the purposes anticipated under the Agreement; and

18.1.3 immediately notify the Disclosing Party if it suspects unauthorised access, copying, use or disclosure of the Confidential Information.

18.2 In spite of Clause 18.1,18.1 a Party may disclose Confidential Information which it receives from the Disclosing Party in any of the following instances:

18.2.1 where disclosure is required by applicable Law, a regulatory body or a court with the relevant jurisdiction if the Recipient Party notifies the Disclosing Party of the full circumstances, the affected Confidential Information and extent of the disclosure;

18.2.2 if the Recipient Party already had the information without obligation of confidentiality before it was disclosed by the Disclosing Party;

18.2.3 if the information was given to it by a third party without obligation of confidentiality;

18.2.4 if the information was in the public domain at the time of the disclosure;

18.2.5 if the information was independently developed without access to the Disclosing Party's Confidential Information;

18.2.6 on a confidential basis, to its auditors or for the purpose of regulatory requirements;

18.2.7 on a confidential basis, to its professional advisers on a need-to-know basis;

18.2.8 to the Serious Fraud Office where the Recipient Party has reasonable grounds to believe that the Disclosing Party is involved in activity that may be a criminal offence under the Bribery Act 2010.

18.3 The Provider may disclose Confidential Information on a confidential basis to Provider Staff on a need-to-know basis to allow the Provider to meet its obligations under the Agreement. The Provider Staff must enter into a direct confidentiality agreement with the MHRA at its request.

18.4 The MHRA may disclose Confidential Information in any of the following cases:

18.4.1 on a confidential basis to the employees, agents, consultants and contractors of the MHRA;

18.4.2 on a confidential basis to any other Central Government Body, any successor body to a Central Government Body or any company that the MHRA transfers or proposes to transfer all or any part of its business to;

18.4.3 if the MHRA (acting reasonably) considers disclosure necessary or appropriate to carry out its public functions;

18.4.4 where requested by Parliament.

18.5 For the purposes of Clauses 18.2 to 18.4 references to disclosure on a confidential basis means disclosure under a confidentiality agreement or arrangement including terms as strict as those required in Clause 18.

18.6 Transparency Information and any Information which is exempt from disclosure by Clause 19 is not Confidential Information.

18.7 The Provider must not make any press announcement or publicise the Contracts or any part of them in any way, without the prior written consent of the MHRA and must use all reasonable endeavours to ensure that Provider Staff do not either.

18.8 The Provider shall ensure that all members of staff comply with the provisions of clause 18.1 and that the YCC Head signs a confidentiality undertaking along the lines of the one contained in Annex 6 of this Agreement.

19 When you can share information

19.1 The Provider must tell the MHRA within 48 hours if it receives a Request For Information.

19.2 In accordance with a reasonable timetable and in any event within 5 Working Days of a request from the MHRA, the Provider must give the MHRA full co-operation and information needed so the MHRA can:

19.2.1 publish the Transparency Information;

19.2.2 comply with any Freedom of Information Act (FOIA) request; and

19.2.3 comply with any Environmental Information Regulations (EIR) request.

19.3 To the extent that it is allowed and practical to do so, the MHRA will use reasonable endeavours to notify the Provider of a FOIA request and may talk to the Provider to help it decide whether to publish information under Clause 19.1. However, the extent, content and format of the disclosure is the MHRA's decision in its absolute discretion.

20 Intellectual property rights

20.1 Each Party keeps ownership of its own Existing IPRs. The Provider gives the MHRA a non-exclusive, perpetual, royalty-free, irrevocable, transferable worldwide licence to use, change and sub-license the Provider's Existing IPR to enable the MHRA and its sub-licensees to both:

20.1.1 receive and use the Deliverables; and

20.1.2 use the New IPR.

20.2 Any New IPR created under the Agreement is owned by the MHRA. The MHRA gives the Provider a licence to use any Existing IPRs and the New IPR for the purpose of fulfilling its obligations during the Term.

20.3 Where a Party acquires ownership of intellectual property rights incorrectly under this Agreement it must do everything reasonably necessary to complete a transfer assigning them in writing to the other Party on request and at its own cost.

20.4 Neither Party has the right to use the other Party's intellectual property rights, including any use of the other Party's names, logos or trademarks, except as provided in clause 20 or otherwise agreed in writing.

20.5 If any claim is made against the MHRA for actual or alleged infringement of a third party's intellectual property arising out of, or in connection with, the supply or use of the Deliverables (an "**IPR Claim**"), then the Provider indemnifies the MHRA against all losses, damages, costs or expenses (including professional fees and fines) incurred as a result of the IPR Claim.

20.6 If an IPR Claim is made or anticipated the Provider must at its own expense and the MHRA's sole option, either:

20.6.1 obtain for the MHRA the rights in clauses 20.1 and 20.2 without infringing any third party intellectual property rights; and

20.6.2 replace or modify the relevant item with substitutes that don't infringe intellectual property rights without adversely affecting the functionality or performance of the Deliverables.

20.7 The Provider shall not use in the delivery of the Deliverables any Third Party IPR unless it has notified the MHRA that the owner or an authorised licensor of the relevant Third Party IPR will grant a direct licence to the MHRA for the Third Party IPR and that licence has been granted. The MHRA, in its absolute discretion, shall have 10 Working Days following the Provider's notification to reject the grant of the licence.

20.8 If the Provider cannot obtain for the MHRA a licence in respect of any Third Party IPR, for whatever reason, the Provider shall:

20.8.1 notify the MHRA in writing; and

20.8.2 use the relevant Third Party IPR only if the MHRA has provided authorisation in writing, with reference to the acts authorised and the specific intellectual property rights involved.

20.9 In spite of any other provisions of the Agreement and for the avoidance of doubt, award of this Agreement by the MHRA and the ordering of any Deliverable under it does not constitute an authorisation by the Crown under Sections 55 and 56 of the Patents Act 1977, Section 12 of the Registered Designs Act 1949 or Sections 240 – 243 of the Copyright, Designs and Patents Act 1988.

20.10 Subject to clause 20.12, the Provider agrees that the MHRA may at its sole discretion publish under Open Licence all or part of the New IPR Items and the Provider warrants that the New IPR Items are suitable for release under Open Licence.

20.11 The Provider will supply any or all New IPR Items in a format suitable for publication under Open Licence ("the Open Licence Publication Material") within 30 days of written request from the MHRA ("MHRA Open Licence Request").

20.12 The Provider may within 15 days of a MHRA Open Licence Request under clause 20.11 request in writing that the MHRA excludes all or part of:

20.12.1 the New IPR; or

20.12.2 Provider Existing IPR or Third Party IPR that would otherwise be included in the Open Licence Publication Material supplied to the MHRA pursuant to clause 20.11 from Open Licence publication.

20.13 Any decision to approve any such request from the Provider pursuant to clause 20.12 shall be at the MHRA's sole discretion, not to be unreasonably withheld, delayed or conditioned.

20.14 Subject to clause 12, the MHRA will not be liable in the event that any Provider Existing IPR or Third Party IPR is included in the Open Licence Publication Material published by the MHRA.

21 Limitation of liability

21.1 Neither Party limits its liability in respect of a breach of this Agreement or in respect of personal injury or death caused by its own negligence, or in respect of fraudulent misrepresentation, nor where liability may not otherwise be limited at law.

21.2 Subject to clause 21.1 neither Party shall be liable to the other for any indirect or consequential loss, damage, injury or costs whatsoever which arise out of or are connected with MHRA's or the Provider's adherence or non-adherence to the terms and conditions of this Agreement.

21.3 Subject to clause 21.1 both Parties limit their liability to the other to a sum not greater than the annual Charges.

22 Public reputation of the parties

22.1 Both Parties recognise the importance of the other Party's public reputation and legal responsibilities. Each Party shall use all reasonable endeavours not to harm or compromise these.

23 Signatories

IN WITNESS WHEREOF, the Parties have executed this Form of Agreement

Signed for and on behalf of the MHRA

Signature:	Name and title:	Date:
Redacted under FOIA Section 40 Personal Info	Redacted under FOIA Section 40 Personal Info	

Signed for and on behalf of the Provider

Signature:	Name and title:	Date:
Redacted under FOIA Section 40 Personal Info	Redacted under FOIA Section 40 Personal Info	1.6.23

ANNEX 1 Objectives

The objectives shall be subject to periodic review or review upon request between MHRA and Provider

1. **Education** – *To educate and inform stakeholders including healthcare professionals and patients about the Yellow Card scheme*

    1.1. To develop and update on-going training programmes for students, including undergraduates and postgraduates, and all healthcare professional stakeholders, including GPs, community pharmacists, hospital pharmacists, hospital doctors and hospital nurses.

    1.2. To provide at least 15 lectures, workshops or other events per year, to educate students and healthcare professionals about medicinal products, ADRs, medications errors, vigilance and the Yellow Card scheme.

    1.3. To maintain regular contact and support local healthcare professionals, Medication and Medical Device Safety Officers (MSOs and MDSOs) or Yellow Card champions or Patient Safety Specialists - where relevant within YCC region to increase awareness levels of Yellow Card scheme and reporting rates.

    1.4. To maintain and expand current network of stakeholders.

2. **Patient Reporting** – *To increase patient awareness of Yellow Card reporting and help drive an increase in patient reporting*

    2.1. To engage with primary care settings such as community pharmacists and GPs to increase patient awareness of Yellow Card reporting.

    2.2. To engage or make contact with at least five to ten local patient groups per financial year, including giving presentations or talks or exploring opportunities for partnership to increase levels of awareness.

    2.3. To develop and maintain strategy programmes which can include talks, for sharing information such as Yellow Card Data, case studies and reporting trends with stakeholders including local patient groups, hospital pharmacists and GPs to promote patient awareness of patient Yellow Card reporting.

3. **External/Stakeholder communications** – *To communicate information about the Yellow Card scheme to stakeholders*

    3.1. To develop and maintain the YCC website, ensuring that they contain easily accessible information on the reporting of ADRs and medicinal products including medical device adverse incidents.

3.2. To ensure that the YCC websites contain accessible links to agreed Yellow Card partners.

3.3. YCCs that wish to communicate information to stakeholders through educational material on their websites are to develop and update these training and resource materials accordingly on their websites, including promoting e-learning modules where e-learning modules are available.

3.4. YCCs to promote and disseminate safety messages from MHRA to YCC stakeholders as required, such as drug safety updates, pharmacovigilance issues, medicinal product safety alerts, including those related to medical devices and e-learning modules.

3.5. To monitor the number of hits on YCC websites.

4. **Facilitation** – *To raise awareness and encourage facilitation of direct Yellow Card reporting from healthcare systems*

4.1. Raise awareness of electronic reporting methods in primary and secondary care such as MiDatabank, SystmOne and the Yellow Card mobile application.

4.2. To identify potential local contacts for further development in this area.

4.3. To provide input to the MHRA on strategy and development of the Yellow Card scheme.

5. **Internal communications** – *To communicate with the MHRA on a regular basis regarding Yellow Card Strategy and reporting from the YCC regions*

5.1. Annual report - YCCs to produce an annual report describing their activities over the past year. The report should be produced and sent to the MHRA within three months of receipt of annual Yellow Card Data from the MHRA.

5.2. Quarterly Teleconference - To participate in a quarterly teleconference between the YCCs and MHRA to discuss progress and share information.

5.3. Yellow Card Strategy – To provide views and input into the Yellow Card Strategy.

5.4. YCCs to provide further information and updates on research and education strategies.

6. **Analysis** – *To analyse quarterly supply of Yellow Card data and identify targets for improvement*

6.1. To identify local areas of low Yellow Card reporting by analysing Yellow Card quarterly data.

6.2. To promote the Yellow Card scheme with the intent of increasing reporting in these areas of low Yellow Card reporting.

6.3. To identify low reporting groups and engage with them to promote the Yellow Card scheme with the intent of increasing reporting.

6.4. To provide MHRA with updates on any other actions taken with the quarterly statistics.

ANNEX 2 YCCYCC specific Liaison Officers

	MHRA
Name	Redacted under FOIA Section 40 Personal Info (as of March 2023)
Title	Yellow Card team and Yellow Card Centre Liaison Officers (YCCLO); Signal Assessors
Address	Medicines and Healthcare products Regulatory Agency 10 South Colonnade Canary Wharf London E14 4PU
Telephone	0800 731 6789
e-mail	MHRA-Regionals@mhra.gov.uk

ANNEX 3 Guidelines for safe disposal of electronic Yellow Card data by YCCs

1. Scope

1.1. This guideline provides a brief on general procedures for the safe disposal of externally held electronic1 Yellow Card Data by Yellow Card Centres.

2. Introduction

2.1. The MHRA and most other modern organisations are increasingly dependent on computer systems. Substantial costs may be incurred if a system, or the information it contains, is lost, damaged, destroyed or if information is obtained by those not entitled to it. Large amounts of valuable information can be easily stored on external computers and portable computing devices, such as laptops, notebooks, smart phones and Personal Digital Assistants (PDA). It is therefore paramount to ensure data are protected by both minimising the amount of information stored and adequately safeguarding it.

2.2. The Data Protection Act 1998 (DPA) applies to personal data. Its purpose is to ensure that such data are processed fairly and lawfully and in particular that personal data are not disclosed to third parties unlawfully. The DPA covers computer records, discs, CDs, USB memory sticks and information held in paper files (e.g. index cards, filing systems etc).

2.3. The seventh data protection principle requires data controllers to ensure that appropriate security measures are in place to prevent the unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data. When the processing of personal data are carried out by a data processor on behalf of the data controller, the Agreement for that processing must require the data processor to comply with obligations equivalent to those imposed on the data controller by the seventh principle.

2.4. Whether the measures in place are appropriate will depend upon whether they provide a level of security appropriate to the harm which might result from a breach of security and the nature of the data to be protected, taking into account the state of technological development and the cost of implementing the measures.

[1] Data/Bits & bytes stored on a digital storage device, e.g. hard disk, flash memory key, CD-ROM etc

3. Background

3.1. The MHRA operates post-marketing surveillance systems for reporting, investigating and monitoring adverse reactions to medicines and adverse incidents involving medical devices to safeguard public health. The safety of medicines is monitored using the Yellow Card scheme which has been in existence since 1964.

3.2. The Independent Scientific Advisory Committee for MHRA database research and the MHRA consider that confidentiality of Yellow Card Data is paramount. For this reason such data are provided to third parties such as the YCCs on stringent conditions. The Yellow Card Data supplied is always anonymised with no personal specific identifiable data and is provided for use for trending analysis for patient safety and geographical promotion.

3.3. Accordingly, the MHRA has provided the information to the YCCs on the following conditions, which in relation to Yellow Card Data must be complied with by any person who is employed or engaged by the centres.

4. Data Use

4.1. Desktop Computers

If you use a desktop Personal Computer (PC) you must:

4.1.1. Have adequate security in place at all times when you are not using it, i.e. lock the office when no one is there.

4.1.2. Ensure that your computer receives regular Operating System security patches, firewall and anti-virus updates

4.1.3. Be familiar with your computer's connection capabilities. If it has network/telephone access, be sure to know how you can securely connect to an authorised network or the Internet. Be sure to disconnect any network/telephone connections and to turn it off when not in use

4.1.4. Understand the level of data you are using. Never store or process information with protective markings unless authorised to do so and in a secure environment

4.1.5. Be aware of your surroundings and of the opportunity for un-authorised people looking 'over your shoulder'

The items above are not exhaustive and provide general pointers to make you aware of the types of issues involved. Any person using desktop, mobile or personal technology must take a precautionary approach to information security.

4.2. Portable computers

Due to risk of theft, portable computers (including PDAs, laptops etc) and USB's **must not** be used to store Non-Aggregated Yellow Card Data unless encrypted. Data must be stored at all times in the location you have told the MHRA.

5. Data Removal Guidelines

5.1. You must be cautious of the fact that in the event your computer is sold or stolen, the data can potentially be accessed by unscrupulous people.

5.2. It is a professional and moral obligation to protect (in accordance with the DPA) sensitive Yellow Card Data which is no longer required, from unnecessary disclosure. When required, data stored on a computer must be carefully disposed of in an efficient and cost-effective manner. The data owner must be certain that Yellow Card Data which is no longer required is obliterated. As the NHS computer system (which YCCs will use to store Yellow Card Data) is part of a secure 'restricted' network (this is the minimum classification level for the NHS, and echoes that of the Department of Health), Yellow Card Data stored on NHS computers can be deleted in the normal way.

5.3. Proper organisation of research data on large storage devices is important as this will allow you to safely locate and clear the data, minimising the risk of accidental erasure. Ideally, Yellow Card Data should be stored under a main folder. In order to manage large amounts of data, other folders should be created, these folders should be created in a hierarchy structure. This will make the task of shredding individual or even large chunks of data files easier and safer.

ANNEX 4 Clarification of types of information that require mhra approval prior to publication

As part of their usual operating arrangements, the MHRA will provide Yellow Card Data to YCCs. It is appropriate that the MHRA should have the opportunity to review and approve documents relating to Yellow Card Data and promotional material since this provides them with the opportunity to correct mistakes or errors in interpretation and also gives an early warning about publications which may have further implications for the MHRA.

It is not necessary or appropriate for MHRA to review all published output from staff associated with YCCs. YCC staff may have other roles which involve publication of articles. Much of this output is unrelated to the MHRA and the Yellow Card scheme, while other publications involve routine communications about the scheme for educational purposes. This document seeks to clarify when MHRA approval is required and when it is unnecessary. There will, inevitably, be some circumstances when the need for approval is unclear. Under these circumstances it is advisable that YCCs seek advice from the MHRA.

Publications about the Yellow Card scheme should carry a disclaimer that opinions expressed are those of the authors and not necessarily those of the MHRA or the Commission on Human Medicines.

The MHRA will provide feedback on all publications sent for review within 28 days.

MHRA approval is not needed for the following:

(A) Papers or other output from Yellow Card Centre staff where the authors are not attributed to the YCC on the paper and where there has been no use of Yellow Card Data.

(B) Academic publications relating to ADRs or adverse medical device incidents where the information comes from the author's own research or clinical experience, or is already in the public domain, even if some of the patients described in the publication may have also been subject to Yellow Card reporting.

(C) Quoting Aggregated data on Yellow Card reporting for educational/promotional purposes e.g. in presentations.

(D) Annual reports of YCC activity produced according to a format agreed with MHRA. These will be published on the YCC website.

Publications that need MHRA approval

(E) Any publications in academic journals or other print media that use Yellow Card Data supplied by MHRA not in the public domain.

(F) Any publications that use analysis and/or interpretation of Yellow Card Data obtained from any other source, including the MHRA website.

(G) Any publication which is attributed to a YCC, or where the author is specifically listed as a YCC staff member or when the publication carries the Yellow Card logo, since such publications might otherwise be considered as a statement of the view of the MHRA or Commission on Human Medicines.

(H) Any publications for media, press or Parliament.

ANNEX 5 Annual report template

Similar to the objectives, this is subject to periodic review or review upon request between MHRA and Provider.

The following is a guide template for producing the annual report. YCCs should not be limited in the production and content of the report but should contain core information set out below:

YELLOW CARD CENTRE [add centre name here]

ANNUAL REPORT TO MHRA

Date:

1. Staff
   a. Full name Job Title
2. Executive summary
3. Yellow Card data – Adverse Drug Reactions
   a. Total numbers - table summarising reports over the last five years in YCC area; line graph

Year	Number of reports	Percentage change on previous year
202X/2X		

   b. Reporter qualifications – clustered column graph for reporter qualifications and number of reports over last two years
   c. Serious reports - table of serious reactions over last five years

Year	Number of serious reports	Percentage of total reports	Percentage change on previous year
202X/2X			

   d. Fatal reports – table summarising fatal reports over last five years

Year	Number of fatal reports	Percentage change on previous year
202X/2X		

Reporter	202X/2X		202X/2X		202X/2X	
	Number	% of total	Number	% of total	Number	% of total
Carer Parent Patient						
Community Pharmacist Hospital Pharmacist Pharmacist Pharmacy Assistant Pre-reg pharmacist						
Hospital Nurse Nurse						
GP Hospital Doctor Physician						
Coroner						
Dentist						
Midwife						

Optometrist						
Radiographer						
Hospital Healthcare Professional						
Healthcare Assistant Other Healthcare Professional						
Medical Student						
Unknown						
Total						

e. Age breakdown – table and clustered bar graph

Age band	202X/2X	202X/2X	202X/2X
Unknown			
Under 2			
2 - 6 years			
7 - 12 years			
13 - 17 years			
18 - 24 years			
25 -34 years			
35 - 44 years			

45 - 54 years			
55 - 64 years			
65 - 74 years			
75+ years			
Total			

f. Top 10 suspected medicines and reactions tables - comparison of last two years

Drug name	Number of reports 202X/2X
e.g. Varenicline (Champix▼)	

g. Sources of reports – detailed breakdown; may need to include method of report e.g. web/named clinical systems etc.

4. Discussion of Yellow Card data

5. Summary of other Yellow Card data (medical devices etc) and discussion

6. Promotional activities

a. Training delivered to healthcare professionals and their respective groups

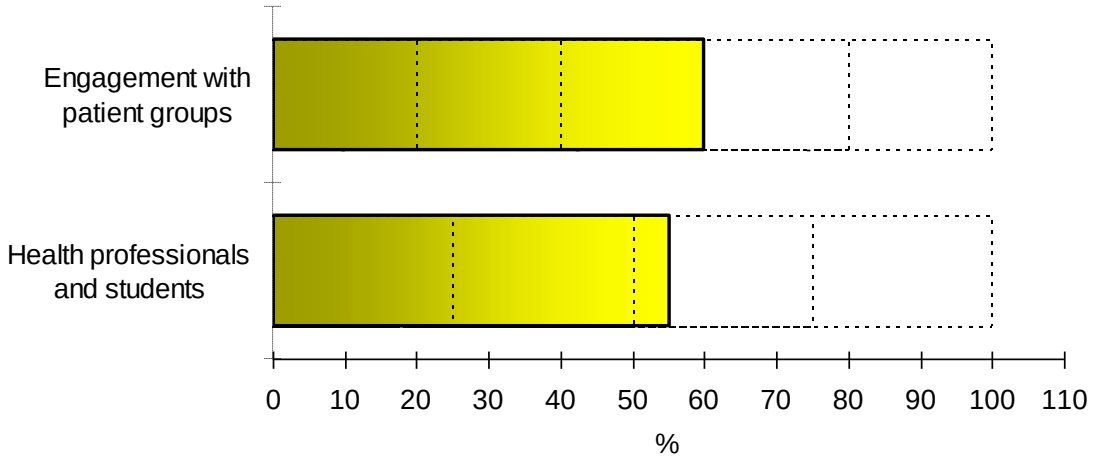
Audience type	Session type	Duration (hours)	Number of sessions	Total audience numbers	Total hours training
Dentists	Lecture	1 hour	1	11	1

b. Training delivered to patients and their respective groups

c. Training delivered to undergraduates

Example graphical summary compared against agreed 1.2 and 2.2 objectives (Annex 1)

[Paste graph from excel as shown below:]



d. Lectures delivered (invited)

e. Materials developed for YCS promotion

7. Publications
8. Documents uploaded to Citrix Share File or Teams Channels:
9. YCC website
    a. Website updates
    b. Number of website hits
10. Research
11. Conclusion
12. Appendix 1 – Progress report summary against objectives

Appendix 1 to Annex 5 – Progress report summary against objectives to be expanded as required by MHRA

General Objectives	Performance measures and targets	Progress at end of year
1. **Education** – *To educate and inform stakeholders including healthcare professionals and patients about the Yellow Card scheme*	1.1. To develop and update on-going training programmes for students, including undergraduates and postgraduates, and all healthcare professional stakeholders, including GPs, community pharmacists, hospital pharmacists, hospital doctors and hospital nurses	
	1.2. To provide at least 15 lectures, workshops or other events per year, to educate students and healthcare professionals about medicinal products, ADRs, medications errors, pharmacovigilance and vigilance of medical devices, and the Yellow Card scheme	
	1.3. To maintain regular contact and support local Medication and Medical Device Safety Officers (MSOs and MDSOs) and Patient Safety Specialists within YCC region to increase awareness levels of Yellow Card scheme and reporting rates	
	1.4. To maintain and expand current network of stakeholders	

General Objectives	Performance measures and targets	Progress at end of year
2. **Patient Reporting** – *To increase patient awareness of Yellow Card reporting and help drive an increase in patient reporting*	2.1. To engage with primary care settings e.g. community pharmacists and GPs to increase patient awareness of Yellow Card reporting	
	2.2. To engage or make contact with five local patient groups per financial year, including giving presentations and talks	
	2.3. To develop and maintain strategy programmes which can include talks, for sharing information such as Yellow Card Data, case studies and reporting trends with stakeholders including local patient groups, hospital pharmacists and GPs to promote patient awareness of patient Yellow Card reporting	
3. **External / Stakeholder communications** – *To communicate information about the*	3.1. To develop and maintain the YCC website, ensuring that they contain easily accessible information on the reporting of ADRs and adverse medical device incidents including Yellow Card data that is reportable	
	3.2. To ensure that the YCC websites contain accessible links to agreed Yellow Card partners	

General Objectives	Performance measures and targets	Progress at end of year
Yellow Card scheme to stakeholders	3.3. YCCs that wish to communicate information to stakeholders through educational material on their websites are to develop and update these training and resource materials accordingly on their websites, including promoting e-learning modules where e-learning modules are available	
	3.4. YCCs to promote and disseminate safety messages from MHRA to YCC stakeholders as required, such as drug safety updates, vigilance issues and alerts for medicinal products including medical devices, and e-learning modules	
	3.5. To monitor the number of hits on YCC websites	
4. **Facilitation** – *To raise awareness and encourage facilitation of direct Yellow Card reporting from healthcare systems*	4.1. Raise awareness of electronic reporting methods in primary and secondary care such as MiDatabank, SystmOne and the Yellow Card mobile application	
	4.2. To identify potential local contacts for further development in this area	
	4.3. To provide input to the MHRA on strategy and development of the Yellow Card scheme	

General Objectives	Performance measures and targets	Progress at end of year
5. **Internal communications** – *To communicate with the MHRA on a regular basis regarding Yellow Card Strategy and reporting from the YCC regions*	5.1. Annual report - YCCs to produce an annual report describing their activities over the past year. The report should be produced and sent to the MHRA within three months of receipt of annual Yellow Card Data from the MHRA	
	5.2. Quarterly Teleconference - To participate in a quarterly teleconference between the YCCs and MHRA to discuss progress and share information	
	5.3. Yellow Card Strategy – To provide views and input into the Yellow Card Strategy	
	5.4. YCCs to provide further information and updates on research and education strategies	
6. **Analysis** – *To analyse quarterly supply of Yellow Card Data and identify*	6.1. To identify local areas of low Yellow Card reporting by analysing Yellow Card quarterly data	
	6.2. To promote the Yellow Card scheme with the intent of increasing reporting in these areas of low Yellow Card reporting	

General Objectives	Performance measures and targets	Progress at end of year
targets for improvement	6.3. To identify low reporting groups and engage with them to promote the Yellow Card scheme with the intent of increasing reporting	
	6.4. To provide MHRA with updates on any other actions taken with the quarterly statistics	

ANNEX 6 Confidentiality undertaking to be signed by the provider/YCC head on behalf of all staff

1 I understand and accept that in the course of carrying out my functions as a Yellow Card Centre it will be necessary for me to receive Confidential Information concerning amongst other things personal information from which it is possible to ascertain the identity of a living individual.

2 I agree and undertake to maintain confidentiality regarding information on reports and related matters and to only use the Non-Aggregated Yellow Card Data or disclose information to any third party.

3 I agree to adhere to the MHRA's IT policies on storage, handling and destruction of data and will adopt best practice.

Signed: Redacted under FOIA Section 40 Personal Info

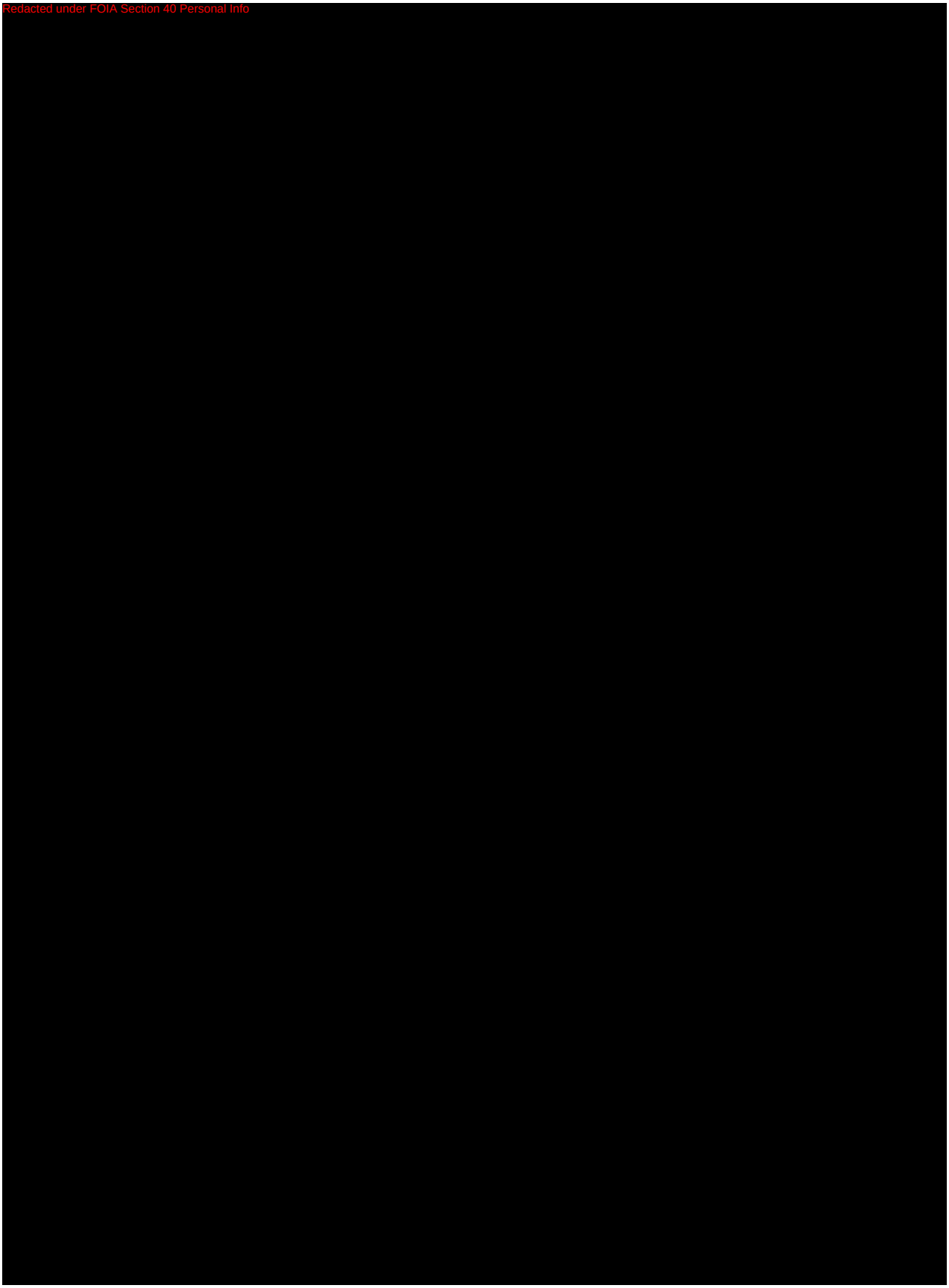
Full nam

Job title:

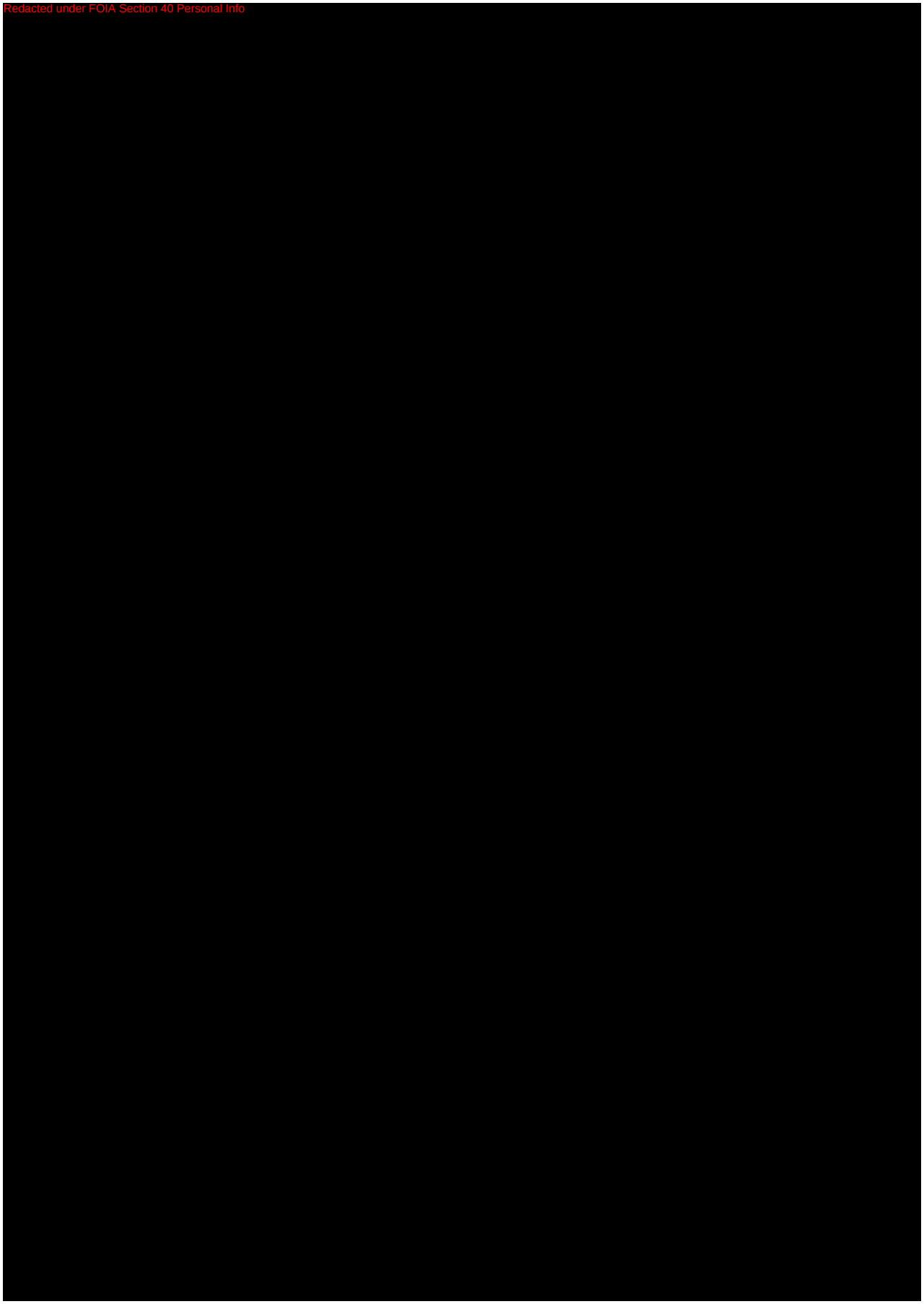
Date: 19 May 2023

ANNEX 7 All YCC contact details

Redacted under FOIA Section 40 Personal Info



Redacted under FOIA Section 40 Personal Info



ANNEX 8 Data protection

1 DATA PROTECTION – PERMITTED PURPOSE

1.1 The Parties agree to only process Personal Data as described in this Agreement and for the Permitted Purpose.

1.2 The Parties shall not process Personal Data in a way that is incompatible with the Permitted Purpose.

1.3 The lawful bases (and conditions or exceptions for processing of any Special Categories of Personal Data or criminal offence data) and the legal power for data sharing are set out in this Annex 8.

2 DATA PROTECTION – JOINT CONTROLLERS

2.1 Where the Parties are acting as Joint Controllers, each Joint Controller shall co-operate with the other Joint Controller as described in this Clause 2.1. Prior to entering into this Agreement, the Parties shall document the details of their Joint Controller relationship by completing the tables in Annex 8 below and any such tables completed by the Parties under this Clause 2.1**Error! Reference source not found.** shall be referred to in this Agreement as the Joint Controller Table. The provisions of this Clause 2 shall apply only to the processing described in the Joint Controller Table.

2.2 When Processing Personal Data under this Clause 2, neither Party is processing Personal Data on behalf of the other as a Processor nor acting as an independent Controller.

2.3 Each Party acknowledges and agrees that they have allocated responsibility between themselves for compliance with certain aspects of the Data Protection Legislation as set out in this Agreement and Annex 8.

2.4 Each Party warrants and undertakes that it will:

2.4.1 make available on request to the Data Subjects a copy of this Agreement, unless (subject to the provisions of Clause 18 and 19 of this Agreement) the clause contains confidential information; and

2.4.2 respond within 72 hours in the event of a Personal Data Breach, and, unless exceptional circumstances apply, respond to Subject Requests within the timescales specified by the UK GDPR, and to enquiries from the Information Commissioner in relation to Personal Data Processed pursuant to this Agreement promptly and in any event within any timescales specified by the Information Commissioner.

2.5 The Parties agree to provide reasonable assistance as is necessary to each other to facilitate the handling of any Personal Data Breach in an expeditious and compliant manner.

2.6 If either Joint Controller appoints a third party Processor to Process the Personal Data it shall comply with Article 28 and Article 30 of the UK GDPR and shall remain liable to the other Joint Controller for the acts and/or omissions of the Processor.

2.7 If a notice is given pursuant to Clauses 3.2.3 or 3.2.4, the Parties will cooperate with a view to settling the request or complaint or responding to the communication amicably in a timely fashion.

2.8 The Parties agree, to respond to any generally available non-binding mediation procedure initiated by a Data Subject or by the Information Commissioner. If they do participate in the proceedings, the Parties may elect to do so remotely (such as by telephone or other electronic means). The Parties also agree to consider participating in any other arbitration, mediation or other dispute resolution proceedings developed for data protection disputes.

2.9 Each Party shall abide by a decision of a competent court in England and Wales or that of the Information Commissioner.

3 DATA PROTECTION – GENERAL OBLIGATIONS

3.1 Each Party shall comply with its obligations under Data Protection Legislation.

3.2 Each Party shall notify the other Party without delay if it, in connection with Personal Data Processed under this Agreement:

3.2.1 receives a Subject Request (or purported Subject Request);

3.2.2 receives a request to rectify, block or erase any Personal Data;

3.2.3 receives any other request, complaint or communication relating to any Party's obligations under the Data Protection Legislation;

3.2.4 receives any communication from the Information Commissioner or any other regulatory authority;

3.2.5 receives a request from any third party for disclosure of Personal Data where compliance with such request is required or purported to be required by law; and

3.2.6 becomes aware of an actual or suspected Personal Data Breach (such notification to be made in any event within 24 hours of becoming so aware),

3.2.7 such notification shall include the provision of further information in phases as details become available.

3.3 If either Party receives any formal inquiry, complaint, claim or threat of action from a third party (including, claims made by a supplier or requests for information made under the Freedom of Information Act 2000) in relation to this MoU, the matter shall be promptly referred to the Data Protection Officer of each Party (or its nominated representative).

3.4 The Parties each agree to provide such assistance as is reasonably required to enable the other Party to comply with Subject Requests within the time limits imposed by the Data Protection Legislation.

3.5 Each Party shall promptly (and without undue delay) report to the other any circumstance of which it becomes aware which may:

3.5.1 mean that this Agreement has not been complied with;

3.5.2 cause any Party to breach the Data Protection Legislation as a result of processing carried out in connection with this Agreement; or

3.5.3 mean that there has been unauthorised processing of any Personal Data that is Processed under this Agreement.

3.6 Neither Party shall transfer Personal Data for which the other Party is the Controller outside of the UK unless the prior written consent of the other Controller has been obtained and the following conditions are fulfilled:

3.6.1 the Controller or the Party transferring the Personal Data ensures that (i) the transfer is to a country approved under the applicable Data Protection Legislation as providing adequate protection; or (ii) there are appropriate safeguards in place pursuant to the Data Protection Legislation; or (iii) one of the derogations for specific situations in the applicable Data Protection Legislation applies to the transfer;

3.6.2 the Data Subject has enforceable rights and effective legal remedies;

3.6.3 the Party transferring the Personal Data complies with its obligations under the Data Protection Legislation by providing an adequate level of protection to any Personal Data that is transferred (or, if it is not so bound, uses its best endeavours to assist the Controller in meeting its obligations); and

3.6.4 the Party transferring the Personal Data complies with any reasonable instructions notified to it in advance by the Controller with respect to the processing of the Personal Data.

3.7 The Parties agree that they shall each ensure that any of the Personal Data they hold pursuant to this Agreement is held in strict confidence and securely and that appropriate technical and organisational information security and processing procedures are established and maintained to ensure that at all times such Personal Data are sufficiently protected by them

against any Personal Data Breach and that they each comply with the requirements of Article 32 of the UK GDPR.

3.8 The Parties shall comply with the provisions of the Data Protection Legislation so far as such provisions apply to the processing carried out under this Agreement.

3.9 The Parties shall designate a Data Protection Officer if required by the Data Protection Legislation.

3.10 The Parties shall co-operate to promptly replace or amend any terms of this Agreement:

3.10.1 with any applicable controller to processor standard clauses or similar terms forming part of an applicable certification scheme (which shall apply when incorporated by attachment to this Agreement); or

3.10.2 to reflect any guidance issued by the Information Commissioner.

Joint Controller Table Part 1 (Data Sharing: data protection impact analysis exert)

1	What is the Permitted Purpose for this data sharing?	Yellow Card Centres are commissioned by the MHRA. Their primary role is to educate and inform stakeholders including healthcare professionals and patients and their stakeholders about the Yellow Card scheme and promote greater awareness of the scheme. Data sent to them by MHRA is to focus their efforts on improving reporting, educating reporters and working with local stakeholders.
2	Describe the Personal Data which is to be shared, including the categories, nature and source (if known)?	Data categories, if reported, are shared: Adverse Drug Reaction (ADR) Number – internal or Medical Device incident Serious reactions (Y/N) – these are reactions that result in or suspect that the product was associated with death, was life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or a birth defect.

		Patient Sex Patient Age (Years) Drug Name Drug Characterisation (suspect/other) Reaction Reporter Qualification e.g. pharmacist, patient, GP Reporter Speciality – e.g. consultant, pharmacist, patient, GP Reporter Address Reporter Postcode Reporter Primary Care Trust Date received by MHRA Reporter type (transmission e.g. app/databases/online website) Reporter Email Domain
3	Has this type of Personal Data been shared previously?	Yes– each quarter a dataset is sent to Yellow Card Centres about reports in their regions to perform their objectives.
4	What is the frequency of the data sharing that is to take place over the duration of this Agreement?	Quarterly data
5	What is the legal basis being relied on to share this Personal Data lawfully?	In the interest of promoting reporting to the Yellow Card scheme locally to educate patients, healthcare professionals and their related organisations in the interest of public health and effective regulation of healthcare products from a vigilance standpoint of monitoring safety.
6.	What is the lawful basis being relied on to share this Personal Data?	The special category data is: • Health data (as per categories in section 2)

	Does any of the Personal Data qualify as Special Category Data? If so, what are the conditions for processing?	See Privacy Policy (section 3) above for conditions for processing.
7	What is the scale, size or volume of the Personal Data to be transferred?	Annually the scheme receives 40,000 reports of suspected adverse drug reactions. So each YCC will receive reports in their respective regions depending on postcode data in the report e.g. YCC Scotland receive ~2,500 rows of data in Q1 2022.
8	What are the categories of Data Subjects?	All reporters – e.g. patients, healthcare professionals, parents and carers.
9	What secure method and format will be used to transfer the Personal Data?	Shared using excel files uploaded to MHRA sharefile in line with MHRA protocols
10	Detail the security provision for the storage of the Personal Data.	Sharefile is accessed controlled
11	State the destination country where the Personal Data will be stored by the Data Recipient. If stored outside the UK or any other country that is deemed adequate for data protection purposes, describe the appropriate safeguards that have been put in place?	UK
12	Has this Agreement been added to the Organisations Record of Processing Activities (RoPA)?	Flagged with Information Asset Owner. There are existing YC RoPA entries.

13	How long will the Personal Data be held after completion of this Agreement (Retention period)?	Provider shall at all times ensure that storage of data is secure and handled as per Agreement. It is a professional and moral obligation to protect (in accordance with the DPA) sensitive Yellow Card Data which is no longer required, from unnecessary disclosure. MHRA only keep your personal data for as long as necessary to fulfil the purpose we collect it for, including reporting or legal requirements as per our privacy policy.
14	How will the Personal Data be destroyed when no longer required?	If no longer required and not needing to be retained in line with relevant legislation, the data should be disposed of by Yellow Card Centres staff, IAO or head or nominated persons.
15	DPO Contact Details	Redacted under FOIA Section 40 Personal Info

ANNEX 9

Joint Controller Table Part 2

Each Party agrees to discharge their obligations under Clause 7 in accordance with the allocation of responsibilities and requirements set out in the following table:

Requirement of Data Protection Legislation	**MHRA responsible for compliance**	**Provider responsible for compliance**	**Further detail**
Provide fair processing information to data subjects as required under Articles 12, 13 and 14 of the UK GDPR	☑	☑	[MHRA] OR [Provider] will provide the Data Subjects of the Personal Data with the Agreed Privacy Notice at the time of first contact with the Data Subject. For these purposes, the Agreed Privacy Notice means two weeks.
Dealing with and responding to Subject Requests (including those under Articles 15 to 22 of the UK GDPR and equivalent requirements of other Data Protection Legislation), enquiries or complaints	☑	☑	[The Parties agree that [MHRA] OR [Provider] will be responsible for dealing with and responding to data subject rights requests, enquiries or complaints. The Parties shall ensure that [MHRA's] OR [Provider's] contact details for this purpose are included in the Agreed Privacy Notice (see above). [MHRA] OR [Provider] shall deal with and respond to each Subject Request, enquiry or complaint it receives in accordance with Data Protection Legislation. In the event that [MHRA] OR [Provider] receives a Subject Request, enquiry or complaint, it shall promptly and without undue delay forward that request, enquiry or complaint to [MHRA] OR [Provider].

Requirement of Data Protection Legislation	MHRA responsible for compliance	Provider responsible for compliance	Further detail
			[MHRA] OR [Provider] shall provide reasonable cooperation and assistance to [MHRA] OR [Provider] to enable [MHRA] OR [Provider] to deal with and respond to each Subject Request, enquiry or complaint in accordance with Data Protection Legislation.
Maintaining a record of processing under Article 30 of the UK GDPR	☑	☑	Each Party shall be responsible for creating and maintaining a record of the processing of Personal Data under its responsibility. Each Party shall, promptly following a request from the other Party, provide the other Party with a copy of its record.
Engaging a data processor under Article 28 of the GDPR	☑	☑	If a Party engages a data processor to process Personal Data, the Party shall ensure that it complies with, as a minimum, the requirements of Article 28 of the UK GDPR (and equivalent provisions of other Data Protection Laws), and that Party shall be wholly liable for the acts and omissions of each of its processors.