3.3   Receipt of communication from the Supplier's Contract Manager's by the Buyer does not absolve the Supplier from its responsibilities, obligations or liabilities under the Contract.

4. Role of the Operational Board

4.1 The Operational Board shall be established by the Buyer for the purposes of this Contract on which the Supplier and the Buyer shall be represented.

4.2 The Operational Board members, frequency and location of board meetings and planned start date by which the board shall be established are set out in the Order Form.

4.3 In the event that either Party wishes to replace any of its appointed board members, that Party shall notify the other in writing for approval by the other Party (such approval not to be unreasonably withheld or delayed). Each Buyer board member shall have at all times a counterpart Supplier board member of equivalent seniority and expertise.

4.4 Each Party shall ensure that its board members shall make all reasonable efforts to attend board meetings at which that board member's attendance is required. If any board member is not able to attend a board meeting, that person shall use all reasonable endeavours to ensure that a delegate attends the Operational Board meeting in his/her place (wherever possible) and that the delegate is properly briefed and prepared and that he/she is debriefed by such delegate after the board meeting.

4.5 The purpose of the Operational Board meetings will be to review the Supplier's performance under this Contract. The agenda for each meeting shall be set by the Buyer and communicated to the Supplier in advance of that meeting.

5. Contract Risk Management

5.1   Both Parties shall pro-actively manage risks attributed to them under the terms of this Call-Off Contract.

5.2   The Supplier shall develop, operate, maintain and amend, as agreed with the Buyer, processes for:

5.2.1   the identification and management of risks;

5.2.2   the identification and management of issues; and

5.2.3   monitoring and controlling project plans.

5.3   The Supplier allows the Buyer to inspect at any time within working hours the accounts and records which the Supplier is required to keep.

5.4   The Supplier will maintain a risk register of the risks relating to the Call Off Contract which the Buyer's and the Supplier have identified.

Annex: Contract Boards

The Parties agree to operate the following boards at the locations and at the frequencies set out below:

Operational Board

This meeting will be held in the main on-line on a monthly basis. However, once every 3/6 months the meeting may be held face-2-face at either an NHSD site or the supplier site to be determined by DigiTrials.

During periods of intense delivery DigiTrials reserve the right to hold meetings more frequently.

There may be a requirement to create sub-groups comprising of both DigiTrials and Supplier staff to work on individual issues as directed by the Operational Board.

NHS DigiTrials

Communication Service – Schedule 20

Improving lives with data and technology

Document filename:	**Call-Off Schedule 20 (Call-Off Specification)**		
Project / Programme	**DigiTrials**	Project	**DigiTrials Comms Support**
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Owner	███████	Version	**FINAL**
Author		Version issue date	**20/06/2022**

Contents

Call-Off Schedule 20 (Call-Off Specification)

1. Purpose

1.0 This Schedule sets out the characteristics of the Deliverables that the Supplier will be required to make to the Buyers under this Call-Off Contract to provide a mailout service on behalf of NHS Digital (NHSD) in support of clinical trials.

2. NHSD Organisation Background

2.0 NHSD is the national information and technology partner to the health and social care system using digital and technology to transform the NHS and social care.

2.1 Founded in 2013, headquartered in Leeds and with over 3500 staff, our systems serve 53M citizens and 1.3M NHS Staff. Our mission is to the harness the power of information and technology to make health and care better.

2.2 At NHSD we:

- Run the core IT infrastructure and services of the health and care system

- Design, build and procure new digital services and systems

- Collect, process, link and disseminate data for the health and care system

- Develop and disseminate IT and data standards

- Are the cyber security partner to the health and care system

2.3 As such we are uniquely positioned to enhance communications between clinical trialists, patients and their general practitioners before, during and after a trial.

2.4 The aim of the NHS DigiTrials Communications Mailout Service is to enhance communications between clinical trialists, patients and other relevant stakeholders throughout the trial lifecycle. In addition, the service aims to enhance participant engagement the patient-centricity throughout the participants research journey.

2.5 The scope covers postal mail, SMS, and email on behalf of clinical trials, sending communications such as, but not limited to, invitations, trial results, patient information sheets, newsletters, and letters of thanks on behalf of clinical trials using a third-party communications provider.

2.6 The plan is to conduct the procurement of a mailing provider over Q1 2021 with a decision being made in May 2022 and the service being up and running by the end of Q2 2022.

3. Service Requirements

3.0 Suppliers will be expected to provide the following Services under the Contract in accordance with the Service Level Performance Measures set out under Call-Off Schedule 14 (Service Levels):

- Prepare sample communication and upload via Proof Approval Portal

- Prepare validated cohort file data

- Produce and send cohort communication once approvals have been obtained. Mailout can be:

   (a) Postal, or

(b)   Digital communication covering email & SMS

- Destruction of validated cohort file within 20 working days/28 calendar days of send date but no earlier than 10 working days/14 calendar days

- Processing of returned cohort communications

- Send returned cohort communications data to NHSD

- Destruction of returned cohort communications within 20 working days/28 calendar days of receipt, but no earlier than 10 working days/14 calendar days

3.1   See Call-Off Schedule 14 for details on performance management and Service Level Performance Measures.

3.2   For further details on security requirements see Schedule 9.

3.3   For further details on contract management see Schedule 15.

3.4   A diagram detailing Communication Mailout Process is provided, below, for information purposes to assist in the understanding of our requirements.

3.5   All file and data transfers will ONLY be done via NHSD secure protocols, which are SEFT and MESH

3.6   There is a requirement for the mailout provider to be able to handle ad-hoc changes and amendments from NHSD and their customers.

3.7   The mailout provider must have secure storage provision for uploaded content e.g., samples files, templates, redacted content and produced communication samples

3.8   The mailout provider must have a process to notify/inform NHSD of whether the batching (or grouping) of communications will save time and/or costs. This functionality should be seamless, on-going, and proactive. This will allow NHSD and their customers to make the relevant decision suitable for every communication

3.9   The mailout provider shall have the ability to deliver the same content in alternative formats and in other languages.

3.10   The mailout provider shall have the ability to generate / manage unique patient reference codes (possibly using QR codes or similar) that enable letters to be scanned to come back into a digital journey.

3.11   The mailout provider shall have the ability show the progress of work done (real time tracking capability) to enable the team to monitor progress. This will include the acknowledgement notification of cohort size received.

3.12   The mailout provider shall have the ability provide daily reporting metrics of all cohort communications, for example - notification of sent, return to sender – email and SMS and opened information.

3.13   The mailout provider shall have the ability to enable the team to specify which email address is shown as the sender of an email communication.

4.   Service Timescales

4.0   The core mailout service needs to be available Monday through Friday, 8am to 6pm UK Local Time. However, there may be occasions, sometimes on very short notice, when the service needs to be available outside of these hours including weekends in order to help support our service delivery needs.

5.   GDPR/DPIA

5.0   Further to section 14 of the Core Terms v3.0.8.

5.1   The General Data Protection Regulation (GDPR) has been in effect since 25th May 2018 outlining rigorous rules on how personal data should be handled, and also allows individuals to have complete control of their personal data.

5.2   For this service it is important that NHSD contract with a supplier that is GDPR compliant. The service supplier must document compliance with ISO27001/-2 standards or similar. In addition, the mailout service supplier must complete the DSP Toolkit as part of the award process. The toolkit can be found at the following link:

Data Security and Protection Toolkit (dsptoolkit.nhs.uk)

5.3   It is a legal requirement under the Data Protection Regulations 2018 that every organisation that processes personal information needs to register with the Information Commissioners Office. The mailout service supplier can do so using the following link:

https://ico.org.uk/for-organisations/data-protection-fee/

5.4   As part of the submission response the prospective supplier will have to provide evidence that both the DSP Toolkit and ICO Registrations have been completed. In addition, the prospective supplier will need to provide details of their GDPR policies, procedures, and processes.

5.5   As part of the procurement process and at regular intervals throughout the duration of any contract NHSD reserve the right to conduct surveys to understand the mailing providers readiness and compliance level with GDPR.

5.6   NHSD also reserves the right to conduct on-site audits of the mailing provider if required.

6.   Demand

6.0   NHSD have created a simplified demand model for the next three years. In order to simplify this, we have made a number of assumptions, including categorisation of trials into the size groupings detailed below.
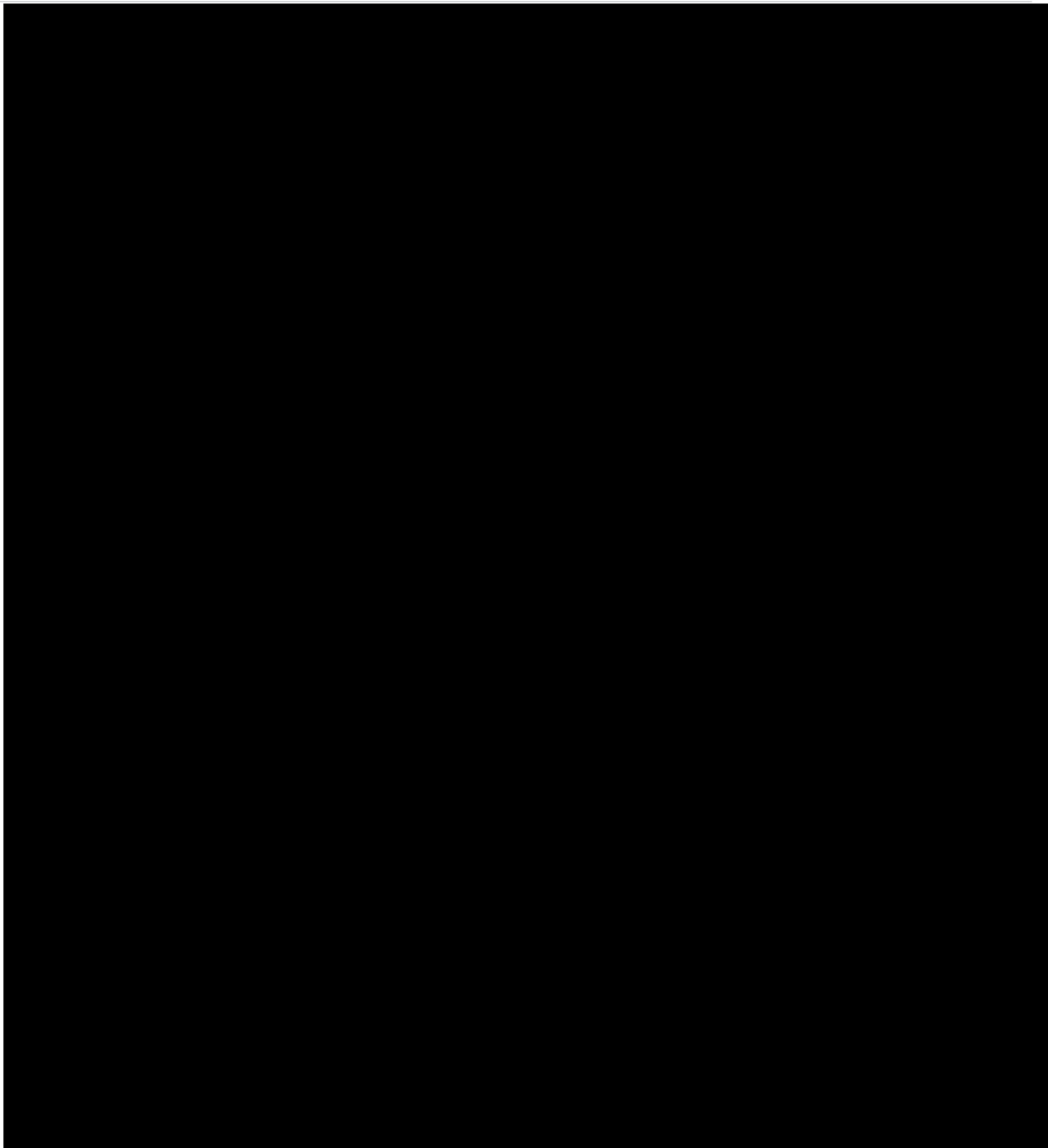
6.1   There are a number of factors that can influence the duration and uptake of a trial that are not factored into our model due to the level of complexity:

- Trial format (virtual vs site-based)

- Number of sites

- Disease / condition being investigated

6.2   The following assumptions have been made when forecasting expected volumes over the next 4 years:

- The demand model is based on NHS DigiTrials Commercial Model of receiving a new Recruitment trial every quarter and new Communication trial bi-

monthly. Additional profiling has been added to categorise small/medium/large trials across the 3-year period, with an optional 4th year

- Assumes that the Recruitment Service will be 100% postal which has been the case to-date but digital invitations may start to be introduced. It is likely that the Communication will want to use a blend of postal and digital (using email and SMS) but volumes of each are yet unknown

- Recruitment volumes are based on █████ uptake of those invited signing up to take part in each study

- Recruitment profiling assumes a ramp up and cool down period

- Assumes that clinical trials come to use NHS DigiTrials in phases (e.g. a study looking to recruit ███████ individuals may be broken down into five phases recruiting ██████ at a time)

7.   Automation of Content Approvals Process

7.0   NHSD are in the process of developing a portal that will for the automation of significant parts of the content approvals process using SharePoint Online, PowerApps, Power Automate and SPFX technologies.

7.1   This portal will facilitate the upload, review and approval of sample communications as described in the Communication process.

7.2   It is a condition of contract letting that suppliers use this portal for all aspects of sample communications once it is operational.

8.   Equality, Diversity, and Inclusion

8.0   Further to section 28 of the Core Terms v3.0.8.

8.1   NHS Digital is committed to promoting equality, diversity, and inclusion.

- Equality is making sure everyone has the same opportunity to participate and fulfil their potential.

- Diversity means employing and promoting people from a variety of backgrounds with different styles, needs, perspectives, values, and beliefs.

- Inclusion is ensuring complete acceptance and a sense of belonging, engagement, and progression for everyone.

8.2   In order to fulfil our organisational commitment to creating a fairer society and an equal, inclusive, and diverse workplace we have set ourselves six objectives.

8.3   We have three Workforce objectives:

- deliver appropriate learning and development to ensure that all staff develop a good level of equality and diversity awareness

- work towards having no difference in the employment outcomes for staff or potential recruits because of protected characteristics

- develop best practice in workforce equality and diversity by creating internal and external networks and supporting positive action initiatives

8.4   We also have three service objectives.

- Guided by industry best practice, when we communicate with the public and service users, we will seek to deliver clearer, more representative, and more accessible information and guidance.

- We will establish a network of staff who will investigate the ways in which we can ensure that our products, policies, and behaviours reflect the communities we serve and do not disadvantage or otherwise negatively impact the public and users of our services.

- As the trusted national provider of high-quality information and data about health and social care, we will improve our focus on protected characteristics in the information that we collect and share. By doing so, we will improve knowledge about the health of, and care experienced by, those with protected characteristics.

8.5   It is therefore important that we engage with suppliers that share those values.

8.6   In particular, for this type of service we may need to be sensitive to the needs of clients whose first language is not English, or those with disabilities (including but not limited to those with hearing or visual impairments).