

# NHS Standard Contract 2023/24

## Particulars (Full Length)

Contract title / ref: Bedfordshire, Luton and  
Milton Keynes ICS

Version 1, March 2023

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(please do not send contracts to this email address)

<b>Contract Reference</b>	<b>C172422</b>
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<b>DATE OF CONTRACT</b>	<b>As per signature</b>
<b>SERVICE COMMENCEMENT DATE</b>	<b>1<sup>st</sup> June 2023</b>
<b>CONTRACT TERM</b>	<b>As set out in section 3.10 of Schedule 2A (Service Specification) subject to early termination</b>
<b>COMMISSIONERS</b>	<b>NHS England</b>
<b>CO-ORDINATING COMMISSIONER</b> <i>See GC10 and Schedule 5C</i>	<b>NHS England</b>
<b>PROVIDER</b>	<b>Name of Provider: ICS Operations t/a Xyla Health &amp; Wellbeing ODS: 8KDO7</b>  <b>Principal and/or registered office address: 9 Appold Street, London, United Kingdom, EC2A 2AP</b>  <b>Company number: 04793945</b>

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## CONTRACT

**Contract title:** NHS Type 2 Diabetes Path to Remission Programme Wave 1 (previously LCD) Lot 4 Bedfordshire, Luton & Milton Keynes

**Contract ref:** C172422

This Contract records the agreement between the Commissioners and the Provider and comprises

1. these **Particulars**, as completed and agreed by the Parties and as may be varied from time to time in accordance with GC13 (*Variations*);
2. the **Service Conditions (Full Length)**, as published by NHS England from time to time at: <https://www.england.nhs.uk/nhs-standard-contract/>;
3. the **General Conditions (Full Length)**, as published by NHS England from time to time at: <https://www.england.nhs.uk/nhs-standard-contract/>.

Each Party acknowledges and agrees

- (i) that it accepts and will be bound by the Service Conditions and General Conditions as published by NHS England at the date of this Contract, and
- (ii) that it will accept and will be bound by the Service Conditions and General Conditions as from time to time updated, amended or replaced and published by, NHS England pursuant to its powers under Regulation 17 of the National Health Service Commissioning Board and Clinical Commissioning Groups (*Responsibilities and Standing Rules*) Regulations 2012, with effect from the date of such publication.

**IN WITNESS OF WHICH the Parties have signed this Contract on the date(s) shown below**

**SIGNED by**

**For and on behalf of NHS England**


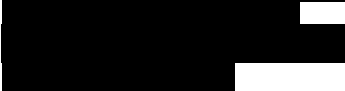
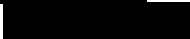

**SIGNED by**

**For and on behalf of ICS Operations t/a Xyla Health & Wellbeing**



## SERVICE COMMENCEMENT AND CONTRACT TERM

<b>Effective Date</b>  <i>See GC2.1</i>	<b>Date of Contract</b>
<b>Expected Service Commencement Date</b>  <i>See GC3.1</i>	<b>1<sup>st</sup> June 2023</b>
<b>Longstop Date</b>  <i>See GC4.1 and 17.10.1</i>	<b>30<sup>th</sup> June 2023</b>
<b>Contract Term</b>	<b>As set out in section 3.10 of Schedule 2A (Service Specification) subject to early termination</b>
<b>Commissioner option to extend Contract Term</b>  <i>See Schedule 1C, which applies only if YES is indicated here</i>	<b>YES</b>
<b>Commissioner Notice Period</b> (for termination under GC17.2)	<p>If the Commissioner exercises its right to terminate pursuant to paragraph 9 of Schedule 1C (Extension of Contract Term) below: 2 months</p> <p>If the Commissioner <u>does not</u> exercise its right to terminate pursuant to paragraph 9 of Schedule 1C (Extension of Contract Term) below: 6 months</p>
<b>Commissioner Earliest Termination Date</b> (for termination under GC17.2)	<p>If the Commissioner exercises its right to terminate pursuant to paragraph 9 of Schedule 1C (Extension of Contract Term) below: the Expected Service Commencement Date</p> <p>If the Commissioner <u>does not</u> exercise its right to terminate pursuant to paragraph 9 of Schedule 1C (Extension of Contract Term) below: 3 months after the Service Commencement Date</p>
<b>Provider Notice Period</b> (for termination under GC17.3)	<b>6 months</b>
<b>Provider Earliest Termination Date</b> (for termination under GC17.3)	<b>3 months after the Service Commencement Date</b>

<b>SERVICES</b>	
<b>Service Categories</b>	<p>Indicate <u>all</u> categories of service which the Provider is commissioned to provide under this Contract.</p> <p><i>Note that certain provisions of the Service Conditions and Annex A to the Service Conditions apply in respect of some service categories but not others.</i></p>
Accident and Emergency Services (Type 1 and Type 2 only) (A+E)	
Acute Services (A)	
Ambulance Services (AM)	
Cancer Services (CR)	
Continuing Healthcare Services (including continuing care for children) (CHC)	
Community Services (CS)	
Diagnostic, Screening and/or Pathology Services (D)	
End of Life Care Services (ELC)	
Mental Health and Learning Disability Services (MH)	
Mental Health and Learning Disability Secure Services (MHSS)	
NHS 111 Services (111)	
Patient Transport Services (non-emergency) (PT)	
Radiotherapy Services (R)	
Urgent Treatment Centre Services (including Walk-in Centre Services/Minor Injuries Units) (U)	
<p>The Parties agree that the Services do not fall under any of the service categories above and therefore the only Service Conditions and provisions of Annex A that apply to the Services are those that are marked with "All".</p>	
<b>Service Requirements</b>	
Prior Approval Response Time Standard  See SC29.25	Not applicable
<b>GOVERNANCE AND REGULATORY</b>	
Nominated Mediation Body (where required – see GC14.4)	CEDR
Provider's Nominated Individual	Name:  
Provider's Information Governance Lead	Name:  

<b>Provider's Data Protection Officer (if required by Data Protection Legislation)</b>	[REDACTED]
<b>Provider's Caldicott Guardian</b>	<b>Name:</b> [REDACTED]
<b>Provider's Senior Information Risk Owner</b>	<b>Name:</b> [REDACTED]
<b>Provider's Accountable Emergency Officer</b>	<b>Name:</b> [REDACTED]
<b>Provider's Safeguarding Lead (children) / named professional for safeguarding children</b>	<b>Name:</b> [REDACTED]
<b>Provider's Safeguarding Lead (adults) / named professional for safeguarding adults</b>	<b>Name:</b> [REDACTED]
<b>Provider's Child Sexual Abuse and Exploitation Lead</b>	<b>Name:</b> [REDACTED]
<b>Provider's Mental Capacity and Liberty Protection Safeguards Lead</b>	<b>Name:</b> [REDACTED]
<b>Provider's Prevent Lead</b>	<b>Name:</b> [REDACTED]
<b>Provider's Freedom To Speak Up Guardian(s)</b>	<b>Name:</b> [REDACTED]
<b>Provider's UEC DoS Contact</b>	<b>Not applicable</b>
<b>Commissioners' UEC DoS Leads</b>	<b>Not applicable</b>
<b>Provider's Infection Prevention Lead</b>	<b>Name:</b> [REDACTED]
<b>Provider's Health Inequalities Lead</b>	<b>Name:</b> [REDACTED]
<b>Provider's Net Zero Lead</b>	<b>Name:</b> [REDACTED]

	Email: [REDACTED]
Provider's 2018 Act Responsible Person	Not applicable
Provider's Wellbeing Guardian (NHS Trusts and Foundation Trusts only)	Not applicable
<b>CONTRACT MANAGEMENT</b>	
<b>Addresses for service of Notices</b>  <i>See GC36</i>	<b>Commissioner:</b> [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]
<b>Frequency of Review Meetings</b>  <i>See GC8.1</i>	Quarterly
<b>Commissioner Representative(s)</b>  <i>See GC10.3</i>	[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]
<b>Provider Representative</b>  <i>See GC10.3</i>	[REDACTED] [REDACTED] [REDACTED] [REDACTED]

## **SCHEDULE 1 – SERVICE COMMENCEMENT AND CONTRACT TERM**

### **A. Conditions Precedent**

The Provider must provide the Co-ordinating Commissioner with the following documents:

1. Evidence of appropriate Indemnity Arrangements
2. Evidence of CQC registration in respect of Provider and Material Sub-Contractors (where required) if required or evidence that CQC registration is not required
3. Evidence that the Provider has employed or engaged a Medical Director as required by section 3.2.12 of the Service Specification
4. Evidence that TDR products that the Provider intends to use comply with all relevant legislation and standards
5. Evidence of compliance with General Conditions 5.11 in relation to Enhanced DBS & Barred List Checks
6. Evidence of compliance with the final paragraph of section 3.2.12 of the Service Specification in relation to:
  - carrying out of Enhanced DBS & Barred List Checks in respect of all members of Staff engaged in the Service who are eligible for such checks;
  - not engaging any person in the Service who is barred from working with vulnerable adults or is otherwise unsuitable for working with vulnerable adults; and
  - ensuring that any Sub-contractor is subject to the same obligations as the two bullet points above

The Provider must complete the following actions:

Not applicable

**SCHEDULE 1 – SERVICE COMMENCEMENT  
AND CONTRACT TERM**

**B. Commissioner Documents**

Date	Document	Description
Not Applicable		

## **SCHEDULE 1 – SERVICE COMMENCEMENT AND CONTRACT TERM**

### **C. Extension of Contract Term**

#### **Extension of Contract Term**

1. As advertised to all prospective providers before the award of this Contract, and as set out in section 3.10 of the Service Specification, the Commissioner may vary the Intervention Period (as defined in the Service Specification) which has the effect of extending the Contract Term.
2. If the Commissioner wishes to exercise the option to extend the Contract Term in this way, the Commissioner will give written notice to that effect to the Provider as set out in section 3.10 of the Service Specification.
3. If the Commissioner gives notice to extend the Intervention Period in accordance with paragraph 2 above, the Contract Term will also be extended and the Expiry Date will be deemed to be the day after which the Provider submits the data submission for the last Service User being provided with the Service who completed the Final Session or other such day as agreed in writing between the Parties.

#### **Changes to Expected Service Commencement Date**

4. The Provider acknowledges and agrees that the Commissioner will be entitled, in its absolute discretion, to:
  - 4.1 amend the Expected Service Commencement Date in accordance with paragraph 5 of this Schedule 1C below; and/or
  - 4.2 terminate this Contract before the then current Expected Service Commencement Date in accordance with paragraph 9 of this Schedule 1C below.
5. Subject to paragraph 6 of this Schedule 1C below, the Commissioner will be entitled to amend the Expected Service Commencement Date not less than 2 months before the Expected Service Commencement Date by notifying the Provider in writing.
6. The Commissioner will be entitled to amend the Expected Service Commencement Date pursuant to paragraph 5 of this Schedule 1C on more than one occasion but the Commissioner will only be entitled to amend the Expected Service Commencement Date to a date that is later than the then current Expected Service Commencement Date. For the avoidance of doubt, the Commissioner will not be entitled to amend the Expected Service Commencement Date if it does not notify the Provider in writing of the amendment at least 2 months before the then current Expected Service Commencement Date and will not be entitled to amend it to a date that is sooner than the then current Expected Service Commencement Date.
7. If the Commissioner amends the Expected Service Commencement Date in accordance with paragraph 5 of this Schedule 1C, the Longstop Date will also be amended accordingly to the day before the new Expected Service Commencement Date.
8. The amendment of the Expected Service Commencement Date and the Longstop Date by the Commissioner in accordance with this Schedule 1C will not constitute a Variation and the provisions of General Condition 13 (Variations) will not apply in relation to such an amendment.
9. The Commissioner will be entitled to terminate this Contract immediately without cause by giving written notice to the Provider not less than 2 months before the then current Expected Service Commencement Date (as it may have been amended in accordance with this Schedule 1C).

10. For the avoidance of doubt, termination under paragraph 9 of this Schedule 1C will be deemed to be termination in accordance with General Condition 17.2.



## SCHEDULE 2 – THE SERVICES

### A. Service Specifications

All defined terms set out in this document reflect the definitions contained within the Contract unless defined in this Schedule 2A

Service Specification No.	1
Service	NHS Type 2 Diabetes Path to Remission Programme
Commissioner Lead	NHS England and NHS Improvement
Provider Lead	
Period	
Date of Review	

#### 1. Overview

##### 1.1 National context and evidence base

Type 2 diabetes represents a major burden on health and care services and its increasing prevalence poses a major risk to population wellbeing and the sustainability of the NHS. Helping people with Type 2 diabetes achieve significant weight loss and improve glucose regulation is likely to reduce the future risk of complications and associated impacts on wellbeing and healthcare costs.

The NHS Long Term Plan published in 2019 announced that a low calorie diet programme would be piloted, at scale, from 2020/21. This commitment built on the approaches of the Diabetes Remission Clinical Trial (DiRECT), and the Doctor Referral of Overweight People to Low Energy total diet replacement Treatment (DROPLET) Randomised Control Trials (RCTs), reflecting the evidence base developed by both of these trials.

Following the pilot phase of the programme, NHS England is making this intervention available to the eligible population across all of England.

##### Introduction to the NHS Type 2 Diabetes Path to Remission Programme

The NHS Type 2 Diabetes Path to Remission Programme (the “NHS T2DR Programme”) is a joint initiative between NHS England and Diabetes UK (Note: the name of the programme is subject to change). The NHS T2DR Programme involves a total diet replacement (TDR) approach that has been shown in RCTs to help some people with Type 2 diabetes achieve and maintain non-diabetic glycaemic levels off all diabetes medication (commonly referred to as remission).

The overall aim of this intervention is to promote weight loss in those that are overweight (BMI of 27 kg/m<sup>2</sup> or over in people from White ethnic groups, adjusted to 25 kg/m<sup>2</sup> or over in people from Black, Asian and other ethnic groups) and recently diagnosed with Type 2 diabetes, achieving remission wherever possible.

Service Users will follow a diet composed solely of nutritionally-complete TDR products, with total energy intake of 800-900 kilocalories a day, for 12 weeks, followed by a period of food reintroduction and subsequent weight maintenance support, with total duration of 12 months.

The Provider must offer a variety of TDR products such as soups, shakes and other suitable products. These must include the availability of varied flavours and textures to support Service User compliance and retention on the NHS T2DR Programme. The Provider must supply the appropriate TDR products to Service Users but must not supply any Service User with more than a four (4) week supply of TDR products at any one time. The Provider must ensure that, at all times during the Contract Term, all TDR products it supplies to Service Users adhere to all legislation and standards that apply to total diet replacement products. To avoid doubt, this includes any legislation and standards as they may be amended, extended or re-enacted from time to time and including any applicable subordinate or replacement legislation or standards. This includes but is not limited to The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 which provide the specific composition and labelling requirements of TDR products. The Provider will be responsible for procuring the TDR products that it supplies to Service Users. The Provider must consider the needs of a variety of potential Service Users, including offering suitable or alternative TDR products where possible for those with intolerances (e.g. lactose intolerance) which may impact on their ability to use certain products.

The identification and referral of people to the NHS T2DR Programme is undertaken by General Practice primary care services (see section 3.2.3). Eligible individuals will be aged 18 - 65 years, diagnosed with Type 2 diabetes within the last 6 years and have a BMI of 27 kg/m<sup>2</sup> or over in people from White ethnic groups, adjusted to 25 kg/m<sup>2</sup> or over in people from Black, Asian and other ethnic groups. Other eligibility criteria also apply and are considered necessary to ensure safety within the context of real-world implementation of this programme. Modelling suggests that 10-20% of those living with Type 2 diabetes would be eligible for the NHS T2DR Programme, once the eligibility criteria are applied (see section 3.2.2 for the full eligibility criteria).

The responsibility of identifying eligible individuals and referring them (once their consent has been obtained) to the NHS T2DR Programme sits with the individual's GP Practice and the Provider is required to verify eligibility with the individual confirming that exclusion criteria have not been met prior to commencement of the intervention in accordance with this Service Specification.

It is intended that, within a defined geographical area, a single provider will deliver the NHS T2DR Programme by offering to individuals the following choice of delivery models:

- One to one face-to-face (the "Face-to-Face Delivery Model");
- One to one digital support (the "Digital Delivery Model"),

References to "the Delivery Models" in this Service Specification are references to both delivery models.

References to "sections" in this Service Specification are references to sections of this Service Specification.

## **2. Outcomes**

### **2.1 Expected outcomes of the NHS T2DR Programme**

- Reduction in weight of Service Users and the maintenance of weight loss achieved;
- Reduced glycaemic parameters in Service Users and achievement of remission of Type 2 diabetes as a result of the intervention;
- Reduction in medication usage among Service Users in line with the intervention;
- Continue to build the evidence base around the effectiveness of a low calorie diet, total diet replacement programme, including evidence around impact of the intervention in different demographic groups.

## **3. Scope**

### 3.1 Aims of the Service

In order to achieve the outcomes set out in section 2.1, the NHS T2DR Programme will aim to:

- Promote weight loss in those that are overweight (BMI  $\geq 27\text{kg/m}^2$  in people from White ethnic groups, adjusted to  $25\text{kg/m}^2$  in people from Black, Asian and other ethnic groups) and recently diagnosed with Type 2 diabetes;
- Support Service Users to adopt a healthier lifestyle, having appropriate regard to achievement of dietary recommendations in England; and
- Maximise completion rates of Service Users, including across groups that share a protected characteristic.

The above aims are for the Service as a whole, and at an individual Service User level goals must be tailored to suit individual Service User requirements.

### 3.2 Service description / care pathway

The Service will comprise:

- An individual assessment of a Service User;
- A period during which the Provider will provide TDR products to the Service User (the “TDR Phase”);
- A period during which the Provider will work with the Service User to reintroduce food into the Service User’s diet (the “Food Reintroduction Phase”); and
- A period during which the Provider will support the Service User in maintaining their weight (the “Weight Maintenance Phase”).

#### 3.2.1 Principles

The Provider will deliver the Service in accordance with the following principles:

- The Provider must provide the Service in accordance with this Schedule 2A and the Annexes and Appendices to this Schedule 2A;
- Delivery of the Service will be tailored to the circumstances and cultural context of Service Users and will be sensitive to different culinary traditions, including where possible for the TDR products themselves;
- The content of the sessions (or, for the Digital Delivery Model, engagement) with Service Users should aim to empower people with Type 2 diabetes to take a leading role in instituting and maintaining long-term behaviour changes;
- The Provider must endeavour to ensure equal access by all Service Users, reduce health inequalities and promote inclusion, tailoring the Service to support and target those with greatest need through a proportionate universalism approach and equality of access for people with protected characteristics under the Equality Act 2010;
- The Provider must monitor service performance and inequalities in outcomes and take appropriate corrective action to improve performance and reduce inequalities accordingly. Specific attention should be given to monitoring and improving performance relating to people with characteristics which have been associated with poorer outcomes in the pilots;
- Access to the Service will accommodate the diverse needs of the target population in terms of availability, accessibility, customs and location, as far as possible;

- The Provider must build relationships and work with relevant local stakeholders (including local health systems and community sector organisations) to deliver a relevant and inclusive programme;
- The Provider should maximise the flexibility (within the scope of this Service Specification) of their offering in order to increase reach for all, including communities who face the most barriers to access;
- The Provider should ensure Service User involvement and engagement in the design, evaluation and improvement of the Service;
- The Provider must engage proactively with GP practices whilst ensuring that the impact on workload for GP practices is minimised;
- All individuals must be treated with courtesy, respect and an understanding of their needs;
- The Provider must supply to GP practices adequate information on the benefits and risks of the Service, in a format which is accessible to potential Service Users and healthcare professionals. The Provider acknowledges that the purpose of providing this information is to support the GP practices' staff to provide information to patients, enabling patients to make an informed choice in accepting referral to the Service;
- All potential Service Users must be given adequate information on the benefits and risks of the Service, in a format which is accessible to them, once a referral has been made but before the Service User begins the Service to allow an informed decision to be made by Service Users before participating in the Service;
- All potential Service Users must also be given information (in compliance with data protection requirements) about how personal data will be used, who will have access to it, and patients' data protection rights (e.g. how to obtain a copy of personal records, rectification, objection, etc);
- All Service Users must be given unconstrained choice between the Face-to-Face Delivery Model and the Digital Delivery Model, with adequate information provided to allow for an informed decision to be made;
- The Provider must provide Service Users with appropriate support throughout the duration of participation in the Service;
- The Provider must ensure that persons referred to the Service are effectively integrated across a pathway including between the Provider of the Service and the GP practice with which the person is registered;
- The Provider must ensure safe, timely and appropriate communication with relevant GP practices for management of adverse or concurrent medical events and for ongoing management at time of discharge, disengagement or drop out from the intervention;
- The Provider must use the template letters to GP practices and Service Users supplied by the Commissioner at all times specified by the Commissioner (including, but not limited to, receipt of referral, notification of TDR start, completion of TDR phase, completion of the programme, discharge from programme). These must be used in the manner and form specified by the Commissioner;
- The Provider must ensure that any contact from GP practices (including, but not limited to, requests for advice on medication adjustments, questions about the referral process, questions about the programme, requests for updates on Service User progress) is responded to appropriately within 5 Operational Days (for avoidance of doubt, this timeline pertains to answering the query rather than simply providing acknowledgement of having receiving such contact)
- Improvements and adjustments to the delivery of the Service may be identified as new evidence emerges from national and international research and local evaluation of the

Service. The Provider acknowledges and agrees that the Service will be adjusted to respond to best available evidence, including (by way of example only) as a result of planned innovation-testing evaluation (e.g. a research project or time-limited pilot of a local innovation to improve the Service). Any such adjustments would be effected as a variation to this Contract in accordance with the variation procedure set out in General Condition 13 (Variations);

- If the Provider identifies emotional wellbeing or mental health issues, the Provider should signpost the Service User to appropriate local services through a process agreed with the local health system prior to the Expected Services Commencement Date.
- If the Provider suspects or identifies behaviours that meet the threshold of an eating disorder during the course of the sessions, the GP practice should be notified and the Service User should be advised to seek care with their GP practice accordingly. In addition, identification of an active eating disorder should be recorded as an adverse event and the process for adverse events followed (as set out in Section 3.2.12).
- The Provider must actively encourage and respond to Service User feedback. This should be sought on all aspects of the Service including the curriculum, programme structure, frequency of support, TDR products, coaching, approach to meeting individual, cultural adaptation, support materials and functionality / usability of any digital tools. The Provider must have effective governance processes for collating and actioning such feedback as well as for responding to any complaints.

In the event and to the extent only of a conflict between any of the provisions of this Service Specification and Appendix 1 (Tender Response Document) and/or Appendix 2 (Local Service Requirements) of this Schedule 2A, the conflict shall be resolved in accordance with the following descending order of precedence:

- this Service Specification;
- Appendix 1 of Schedule 2A (Tender Response Document);
- Appendix 2 of Schedule 2A (Local Service Requirements).

Where Appendix 1 of Schedule 2A (Tender Response Document) or Appendix 2 of Schedule 2A (Local Service Requirements) contains provisions which are more favourable to the Commissioner in relation to the Service Specification and/or Appendix 1 of Schedule 2A (Tender Response Document) as relevant, such provisions of Appendix 1 of Schedule 2A (Tender Response Document) or Appendix 2 of Schedule 2A (Local Service Requirements) shall prevail.

The Commissioner shall in its absolute and sole discretion determine whether any provision in Appendix 1 of Schedule 2A (Tender Response Document) or Appendix 2 of Schedule 2A (Local Service Requirements) is more favourable to it in relation to the Service Specifications and/or Appendix 1 of Schedule 2A (Tender Response Document) as relevant.

### **3.2.2 Eligible population**

Individuals who satisfy all the following eligibility criteria may be referred to the Service:

- Aged 18 to 65 years;
- Diagnosed with Type 2 diabetes within the last 6 years;
- A BMI of 27kg/m<sup>2</sup> or higher in people from White ethnic groups, adjusted to 25kg/m<sup>2</sup> or higher in people from Black, Asian and other ethnic groups.
  - BMI obtained from self-measured weight by a Service User is acceptable for referral. If this cannot be obtained, a clinic-measured value within the last 12 months may be used, provided there is no concern from the referrer that the Service User's weight may have reduced since last measured such that the individual would not be eligible for the Service at present;
- A HbA1c measurement taken within the last 12 months, with values as follows:

- If on diabetes medication, HbA1c 43 to 87 mmol/mol; or
- If not on diabetes medication, HbA1c 48 to 87 mmol/mol;

provided there is no concern from the referrer that the Service User's HbA1c may have changed since last measured such that the individual would not be eligible for the Service at present; and

- Have attended for monitoring and diabetes review when this was last offered, including retinal screening, and commit to continue attending annual reviews, even if remission is achieved. (For avoidance of doubt, if a Service User is newly diagnosed then there is no requirement to wait for retinal screening to take place before offering referral)

Individuals who meet any of the following exclusion criteria must not be referred to the Service and must not be accepted by the Provider. The Provider must confirm that the individual is eligible and so does not meet any of the following exclusion criteria prior to the individual's commencement of the intervention:

- Current insulin user;
- Pregnant or planning to become pregnant within the next 6 months;
- Currently breastfeeding;
- Discharged in the last 12 months from the NHS Type 2 Diabetes Path to Remission Programme after having commenced the programme (for clarity, this does not apply to people previously referred to the programme but who dropped out or declined prior to commencing the TDR Phase);
- Has at least one of the following significant co-morbidities;
  - active cancer;
  - heart attack or stroke in last 6 months;
  - severe heart failure (defined as New York Heart Association grade 3 or 4);
  - severe renal impairment (most recent eGFR less than 30mls/min/1.73m<sup>2</sup>);
  - active liver disease other than non-alcoholic fatty liver disease (NAFLD) (i.e. NAFLD is not an exclusion criterion);
  - active substance use disorder;
  - active eating disorder (including binge eating disorder);
  - porphyria; or
  - known proliferative retinopathy that has not been treated (this does not exclude individuals who are newly diagnosed and have not yet had the opportunity for retinal screening);
- Has had bariatric surgery; or
- Health professional assessment that the person is unable to understand or meet the demands of the NHS T2DR Programme and/or monitoring requirements (due to physical or psychological conditions or co-morbidities).

At time of referral to the Service, the referrer is responsible for discussing and agreeing any relevant medication changes with the potential Service User. The Provider must take steps to ensure that referrers can obtain advice from the Provider regarding medication changes and the Provider must ensure that communication in this regard is facilitated between referrers and the Provider's Medical Director (or another suitably experienced registered medical practitioner within the meaning of Schedule 1 of the Interpretation Act 1978 with an MRCP or MRCGP). Any requests for advice should be responded to with appropriate advice within 5 Operational Days. The Provider acknowledges that

clinical responsibility for an individual's medication changes remains with general practice at all times that the individual is associated with the Service.

It should be made clear by the referrer to the potential Service User that these changes should only be enacted on the first day of starting the TDR intervention. The Provider must be aware of whether any potential Service User has a medication change or not. The Provider must ensure that it has received in writing from the referrer either details of medication changes or confirmation that no medication changes are required. The Provider must ensure the potential Service User is also aware of the medication changes proposed (or that no medication changes are required) although there is no requirement for this to be submitted to the Service User by the referrer in writing. The Provider must ensure that, prior to the first day of TDR Phase, the Service User understands the specific medication changes which are required (or that no medication changes are required). The referrer should also confirm with the Service User that, should they proceed on the NHS T2DR Programme, the Service User:

- Agrees to continue attending yearly diabetes review appointments at their GP practice, regardless of whether remission is achieved;
- Will contact their GP practice or urgent care service as appropriate if they have any unexpected or concerning symptoms which are considered urgent; and
- Will notify their GP practice if they disengage or drop out before the end of their intervention.

The Provider is required, as set out in more detail in section 3.2.5, to confirm that it and the Service User have been provided with information relating to medication changes prior to commencement of the intervention.

### **3.2.3 Referral and Acceptance**

The Service will commence when the Provider begins to accept referrals from the local health systems. As set out in General Condition 3 of the Contract, the date the Provider is required to commence the Service (and so accept referrals) is the later of:

- the Expected Services Commencement Date; and
- the day after the date on which all Conditions Precedent are satisfied.

The Provider and the Commissioner may agree to substitute the Expected Services Commencement Date with any earlier date in which case the Contract will be varied in accordance with its provisions.

The Provider will develop and agree detailed referral protocols with local health systems prior to receiving referrals to the Service. Referrals will come from GP practices. If there is agreement by the Provider, the local health system and the Commissioner, the Parties may agree to amend this Service Specification to include other referral routes.

All individuals who satisfy the eligibility criteria and are not excluded in accordance with section 3.2.2 will be invited by the Provider to participate in the Service as further detailed in section 3.2.4.

The first communication sent by the Provider to the relevant Service User's GP practice on receipt of a referral should make clear that any changes in eligibility to participate in the Service or medication changes (including in particular (but not limited to) new glucose-lowering agents / BP-lowering agents) should be communicated urgently to the Provider. The Provider will confirm with the relevant Service User, prior to starting the TDR Phase, that they have not started any new medications (including in particular (but not limited to) glucose-lowering or blood pressure-lowering medications) since medication changes to take place on the first day of TDR were agreed with their referrer. Where there is concern such changes may have occurred and may require re-consideration of medication changes (e.g. if new glucose-lowering agents / BP-lowering agents have been started), the Provider should contact the GP practice for confirmation that it remains appropriate for the Service User to proceed with the TDR Phase and to request an update on medication changes to take place on the first day of TDR (these would need to be agreed by the referrer and Service User).

### **3.2.4 Invitation to participate**

Subject to the Intervention Cap and Intervention Period (referred to in section 3.10), the Provider will invite all eligible, referred individuals to participate in the Service.

The Provider will initiate contact with each individual directly referred to them (where there is no evidence for ineligibility), within five Operational Days of receipt of the referral, inviting the individual to participate in the Service. The individual must be provided with adequate information about the Delivery Models to allow for an informed, unrestricted choice about which Delivery Model would better suit their needs and individual context.

The Provider will work with local health systems to manage the trajectory of referrals in line with the volume of contracted interventions and work together with the local health system and with the Commissioner to match supply and demand across the duration of the Contract.

The invitation and all follow-up contact will contain accessible information about Type 2 diabetes, the potential to achieve remission, the nature of the intervention and the requirements for Service Users. All contact made with individuals should be grounded in behavioural insight theory and evidence.

Where there is no response from the individual as a result of the initial invitation, the Provider must make at least two additional attempts to contact that individual via at least two of the following methods within a period of one calendar month from the date of receipt of referral: letter, phone call, text message or email.

#### **Where contact has not been established after one month**

If it has not been possible to make contact after a minimum of three attempts and through at least two different channels after one calendar month, the Provider must discharge the individual back to their GP practice. The Provider must also communicate a discharge notice to the individual and signpost the individual to the NHS website pages related to weight management, appropriate physical activity and healthy lifestyles and to any other locally available resources for supporting weight loss, healthy eating and appropriate physical activity.

#### **Where contact has been established**

Where contact has been established but an individual indicates that they do not accept an invitation to participate in the Service, then the Provider must discharge that individual back to the GP practice. The Provider must communicate a discharge notice to the individual's GP practice and the individual and signpost that individual to the NHS website pages related to weight management, physical activity and healthy lifestyles and to any other locally available resources for supporting weight loss, healthy eating and physical activity.

Where contact has been established and an individual accepts an invitation to participate in the Service, the Provider must offer as much choice of dates and times (and, for Face-to-Face Delivery Models, appropriate venues) as logistically possible, where applicable, to attend or participate in an Individual Assessment (which is explained further in 3.2.5 below) provided that the dates and times offered by the Provider are within a period of one calendar month of the date the Provider established contact with the individual and the individual accepted the invitation to participate in the Service. If driven by Service User choice and a decision to defer starting the TDR Phase to a more suitable time, Individual Assessment may occur within 90 days of the referral.

At the point the individual accepts the offer to attend or participate in the Individual Assessment, that individual is considered to be a Service User.

The Provider must comply with any template letters or discharge communication content that the Commissioner notifies the Provider must be used. The Provider must ensure sound data collection mechanisms are in place to support evaluation of the Service in achieving defined outcomes and enable the assessment over time of progress relating to diabetes remission and reductions in the long term complications of Type 2 diabetes and associated morbidity and mortality.

In addition to use of the template letters, the Provider will work closely with the local health system to identify and implement any further locally appropriate mechanisms for ensuring data about a Service User is communicated to the GP practice with which the Service User is registered (using



SNOMED codes where appropriate) and that such data can be integrated within GP clinical systems; ideally by electronic transfer. The Provider will also work with the local health systems to ensure that there is a monthly update on referral and uptake rates, waiting list size and outcomes at locally-agreed levels; e.g. at the level of individual GP practices, Primary Care Networks (PCNs) or ICSs.

The Provider must highlight to the Commissioner and the local health system any issues in relation to referrals and uptake into the Service and any deviation from the expected referral and uptake numbers (as agreed with the local health system).

Additionally, the Provider must notify GP practices about progression of Service Users through the Service through use of the template letters provided by the Commissioner in addition to any further locally agreed means.

### 3.2.5 Individual assessment

The Provider will conduct individual assessments with all Service Users who accept the invitation to participate in the Service ("Individual Assessment").

The Provider will use Individual Assessments to:

- verify the eligibility of the Service User;
- explain in detail the rationale and requirements of the Service; and
- determine whether the Service User wishes to continue with the Service.
- confirm the Service User's choice of Delivery Model.

If the Service User chooses to proceed to the TDR Phase, the Provider will set a mutually-agreeable start date with the Service User and confirm matters relating to any medication changes that will be enacted by the Service User on this same date as set out in this Service Specification.

The Individual Assessment may be undertaken remotely in the Face-to-Face Delivery Model providing this does not restrict the Individual Assessment process in any way and allows for the required information to be obtained and eligibility to be verified. (It is expected that all Individual Assessments will occur remotely in the Digital Delivery Model).

Following the Individual Assessment, confirmation of the Individual Assessment must be sent to the Service User's GP practice. This should include:

- notification regarding whether the Service User intends to proceed to the TDR Phase;
- details of the mutually-agreed start date of the TDR Phase;
- confirmation of any medication changes which will be enacted on the first day of the TDR Phase (or that no changes are required) (as communicated to the Service User and supplied in writing to the Provider by the referrer); and
- confirmation that the Service User:
  - agrees to continue attending yearly diabetes review appointments at their GP practice, regardless of whether remission is achieved;
  - will contact their GP practice or urgent care service as appropriate if they have any unexpected or concerning symptoms which are considered urgent; and
  - will notify their GP practice if they disengage or drop out before the end of the intervention.

Data must be gathered at all points of Service delivery in accordance with the requirements of this Service Specification and Schedule 6A. If a specific data item is indicated in Schedule 6A to be gathered at a specific point of Service delivery, the Provider will gather such data item.

If a Service User has previously accepted the Service but fails to attend or participate in a scheduled and agreed Individual Assessment, the Provider must make at least two further attempts to offer an Individual Assessment at times appropriate to the Service User provided that such times are within one calendar month of the date the Service User failed to attend or participate in the scheduled and agreed Individual Assessment, but no later than 90 days following referral. If the Service User does not complete an Individual Assessment during this time, the Service User should be discharged back to their GP practice, signposting the Service User to the NHS website pages related to weight management, physical activity and healthy lifestyles and to any other locally available resources for supporting weight loss, healthy eating and physical activity.

If, following the Individual Assessment, a Service User:

- does not attend or participate in the first session (or, in the Digital Delivery Model, the first episode of engagement) within 90 days of Individual Assessment;
- does not attend or participate in the first session (or, in the Digital Delivery Model, the first episode of engagement) after the Provider has offered the first session (or, in the Digital Delivery Model, the first episode of engagement) on three separate occasions at times, and for the Face-to-Face Delivery Model, venues, appropriate to the Service User;
- defers attendance at or participation in the session (or, in the Digital Delivery Model, the first episode of engagement) after the Provider has offered the first session (or, in the Digital Delivery Model, the first episode of engagement) on three separate occasions at times, and for the Face-to-Face Delivery Model, venues, appropriate to the Service User; or
- declines the Service,

the Service User should be discharged back to their GP practice, signposting the Service User to the NHS website pages related to weight management, physical activity and healthy lifestyles and to any other locally available resources for supporting weight loss, healthy eating and physical activity.

The Provider must offer the first session (or, in the Digital Delivery Model, the first episode of engagement) within 30 days of the Individual Assessment. For the Face-to-Face Delivery Model, this must be at a venue appropriate to the Service User. If driven by Service User choice and a decision to defer starting the TDR Phase to a more suitable time, the first session may occur within 90 days of the Individual Assessment.

If the Provider cancels any booked session (or, in the Digital Delivery Model, any booked episode of engagement) for any reason at any time during a Service User's participation in the Service, the Provider must promptly reschedule the Service User's session (or, in the Digital Delivery Model, the episode of engagement).

The Provider must record details about the number of contact attempts made to offer the Service, arrange Individual Assessments and rearrange sessions (or, in the Digital Delivery Model, episodes of engagement) including date and method of contact as set out in this section. The Provider is required to record all of this information under Schedule 6A and must share this information with the Commissioner in accordance with the requirements of this Contract and, if relevant, at any other time requested by the Commissioner.

### **Intervention commencement**

Following the Individual Assessment, if the Service User has decided to proceed with the TDR Phase, the Provider must notify the Service User's GP practice of the agreed start date of the TDR Phase. This must be within 90 days of the Individual Assessment. Although necessary medication changes, if applicable, should have been discussed at time of referral, any changes must not be enacted by the Service User until the first day of the TDR Phase. The Provider must, prior to the first day of the TDR intervention:

- ensure that the Provider and the Service User understand the specific medication changes which are required (or that no medication changes are required) and the Provider has

received details of changes (or confirmation that no change is necessary) in writing from the referrer;

- confirm that no additional glucose-lowering or blood pressure-lowering medications have been started since medication changes were last agreed (including if the recommendation was for no medication changes to take place) and specified in writing to the Provider and communicated to the Service User); and
- confirm with the Service User that they will not be taking sulphonylureas, meglitinides or SGLT2 inhibitors as of the first day of the TDR intervention.

If the Provider:

- cannot confirm that the Provider and the Service User have been provided with confirmation from the referrer of the specific medication changes which are required (or that no medication changes are required); and/or
- cannot confirm that no additional glucose-lowering or blood pressure-lowering medications have been started since medication changes were last communicated by the referrer (including communication of no medication changes to be made); and/or
- cannot confirm with the Service User that they will not be taking sulphonylureas, meglitinides or SGLT2 inhibitors (if applicable) as of the first day of the TDR intervention,

then the Provider must defer the Service User's TDR Phase start date and take such action as it necessary to ensure that the above matters are confirmed. Once the matters above have been confirmed, the Provider must promptly arrange the Service User's commencement of the TDR Phase.

### 3.2.6 Intensity and duration of the Service

The Provider must deliver the Service in accordance with the requirements set out in this section.

#### TDR Phase

- The TDR Phase begins from the first day the Service User starts taking TDR products and lasts for 12 weeks.
- An individual should not start taking TDR products and/or commence the TDR Phase or a rescue package (as defined later in this Specification) at any time if they are taking sulphonylureas, meglitinides or SGLT2 inhibitors.
- If the Service User cannot confirm to the Provider that they are not taking sulphonylureas, meglitinides or SGLT2 inhibitors during the TDR Phase or at the commencement of a rescue package or the recommencement of the TDR Phase following a planned pause, the Provider should contact the Service User's GP practice to obtain confirmation as to whether the Service User is or is not taking sulphonylureas, meglitinides or SGLT2 inhibitors. An individual should not start taking TDR products and/or commence or re-commence the TDR Phase or a rescue package (as defined later in this Specification) at any time unless it is confirmed that they are not taking sulphonylureas, meglitinides or SGLT2 inhibitors.
- If the Service User confirms to the Provider that they are taking sulphonylureas, meglitinides or SGLT2 inhibitors during the TDR Phase or at the commencement of a rescue package, the Provider must advise the Service User to cease taking TDR products immediately and the Provider must refer the Service User to their GP practice.
- The Provider must provide TDR products to each Service User for the duration of that Service User's participation in the TDR Phase. The Provider must offer a variety of TDR products such as soups, shakes and other suitable products. These must include the availability of varied flavours and textures to support Service Users' compliance and retention on the Service. The Provider must not supply any Service User with more than a four (4) week supply of TDR products.

- The Contract requires the Provider to perform all its obligations under this Contract in accordance with the Law (as set out in Service Condition 1.1). This requires the Provider to comply with all applicable legislation in relation to the TDR products. The Provider is also required to ensure all TDR products provided to a Service User comply with all standards that are applicable to total diet replacement products. To avoid doubt, this includes any legislation and standards as they may be amended, extended or re-enacted from time to time and including any applicable subordinate or replacement legislation or standards.
- Subject to the three bullet points immediately following this bullet point, TDR products must be provided to replace all daily meals from the first session (or, in the Digital Delivery Model, the first episode of engagement) of the TDR Phase for 12 weeks, with support to ensure that Service Users can adhere to the regimen. Total energy intake should be 800 – 900 kilocalories daily.
- If during the TDR Phase or during the use of a rescue package, the BMI of the Service User has decreased below 21 kg/m<sup>2</sup> in people from White ethnic groups or below 19 kg/m<sup>2</sup> in people from Black, Asian and other ethnic groups, the Provider must cease TDR for the Service User and move the Service User to the Weight Maintenance Phase.
- Where Service Users are unable to comply with full TDR and are at high risk of dropping out of the NHS T2DR Programme, they may, at any point, introduce firstly a single meal of non-starchy vegetables. If they remain at high risk of disengagement, they may further substitute a single TDR meal for a nutritionally appropriate meal of no more than 300 calories. The Provider must set out the point at which Service Users start to replace TDR products with an alternative meal.
- If an individual Service User has specific needs that can't be addressed due to a lack of any compliant TDR product then consideration can be given to alternative approaches for that individual Service User.
- All Service Users must receive fibre supplements from the Provider prior to starting the TDR Phase (and any subsequent periods of TDR such as rescue packages) and the Provider will advise Service Users that they should start taking these from the first day of TDR. The dose provided will equate to 7g per day (usually issued in 2 x 3.5g portions of Ispaghula Husk/Psyllium Husk/Fybogel) during the TDR Phase (and during any rescue packages). Service Users will continue to receive these supplements from the Provider until the relevant Service User advises the Provider that these are no longer necessary. Service Users may be able to stop the fibre supplement on re-introducing meals in the food re-introduction phase. After stopping or decreasing fibre supplementation, if a Service User subsequently indicates a need for further fibre supplementation, the Provider will provide the Service User with further fibre supplements and will continue to provide these.
- If the Service User becomes pregnant, the Provider must immediately discharge the Service User from the Service to the care of the Service User's GP practice.
- If an adverse event occurs, the Provider's Medical Director will decide whether it is appropriate for the Service User to continue with the Service without any changes, or whether appropriate modifications may be made, or to stop the Service User's participation in the TDR Phase but enable the Service User to continue participation in the Service within the requirements of the Service Specification, or whether the Service User should be discharged. If the Provider's Medical Director decides that it is appropriate to enable the Service User to continue with the Service despite the adverse event, the Service User will progress to the Food Re-introduction Phase and then to the Weight Management Phase in accordance with this Service Specification unless any relevant variations to this Service Specification are agreed in relation to that Service User in advance by the Commissioner. However, if it is established that the Service User cannot tolerate the TDR products within the first 2 weeks of the TDR Phase, the Provider must discharge the Service User from the Service to the care of the Service User's GP practice.

- The Provider must ensure that Service Users receive appropriate advice, tools and support in preparation for the Food Re-introduction Phase and the transition to healthy eating. This includes healthy dietary plans appropriate to their preferences and culinary traditions.

### **Food Re-introduction Phase**

- This phase immediately follows the 12 week TDR Phase and lasts for 6 weeks.
- Service Users will gradually re-introduce food using a stepped approach.
- At the latest, the Service User should have ceased using TDR products by the end of 18 weeks following commencement of the TDR Phase.
- During this Food Re-introduction Phase the focus is on the transition from TDR to a balanced diet.
- The Provider must support the Service User to achieve appropriate calorie intake and nutritional balance from food, with targets set according to the Service User's preference for maintaining their weight or aiming for further controlled weight loss and improved diet quality through nutritional and behaviour change support.
- Advice and dietary plans should be tailored to the Service User's individual needs, preferences and culinary traditions.

### **Weight Maintenance Phase**

- This phase follows the Food Reintroduction Phase and comprises the remainder of the programme. The programme is 52 weeks in total.
- During this Weight Maintenance Phase the focus is per Service User preference, for maintaining a steady weight or aiming for further controlled weight loss (except that if the BMI of the Service User has decreased below 21 kg/m<sup>2</sup> in people from White ethnic groups or below 19 kg/m<sup>2</sup> in people from Black, Asian and other ethnic groups as set out in the section under TDR Phase above, the Provider must not support further weight loss) and ensuring changes are embedded for the longer term.
- The Provider must support the Service User to set tailored achievable short, medium and long term dietary and physical activity goals.
- The Provider must support the Service User to ensure appropriate energy intake, and steady increases in appropriate physical activity to meet their individualised weight maintenance goals.
- If a Service User regains 2kg or more, with reference to the lowest weight recorded for that Service User since the completion of the TDR Phase, at any time during the Weight Maintenance Phase, the Provider must offer Service User a relapse management protocol, also referred to as a "rescue package", which includes the reintroduction of TDR for a period of 4 weeks with weekly support sessions.
- The Provider must ensure that the default offer for the rescue package is full TDR for a period of 4 weeks and the Provider must encourage the Service User to accept full TDR. If, however, full TDR is declined by the Service User, a partial rescue package may be offered, consisting of 2 meals replaced with TDR products for a period of 4 weeks. Regardless of whether the rescue package is full or partial, the Provider must ensure there are weekly support sessions during the period of the rescue package;
- The Provider shall not put in place more than one rescue package for any Service User and shall not put in place a rescue package for any Service User after the end of week 42 (as calculated in accordance with the "Minimum session/engagement requirements" section below).

- The Provider will closely monitor and support the Service User during the rescue package. This should be in line with the monitoring requirements of the TDR Phase, with blood glucose and weight measurements taken weekly. Where a Service User is on medication(s) that affects blood pressure (this may include medications used for other purposes such as diuretics for heart failure or alpha-blockers for BPH), the Service User should return to weekly blood pressure monitoring during the rescue package.
- The Provider must put in place an individualised plan for each Service User for food re-introduction for that Service User following a rescue package being implemented. The food re-introduction plan may be up to 6 weeks in duration.

### **Minimum session/engagement requirements**

For the Face-to-Face Delivery Model, the Service must consist of defined sessions.

For the Digital Delivery Model the Service must consist of defined contacts or episodes of engagements between the Provider and the Service User. The minimum requirements of these defined contacts or episodes of engagement are set out in sections 3.2.8 and 3.2.9. Engagement methods that are relevant to the different Milestones are set out in Schedule 3C.

These episodes of engagement or contacts, that comply with the minimum requirements set out in section 3.2.8 and 3.2.9 (as applicable) and as referred to in Schedule 3C are referred to simply as episodes of engagement in this Service Specification.

The minimum defined episodes of engagement are set out below.

Additional sessions (or, in the Digital Delivery Model, episodes of engagement) may be provided to support engagement, retention and achievement of intended outcomes.

The Provider must provide the following minimum sessions (or, in the Digital Delivery Model, episodes of engagement) with a Service User during the Service, constituting an overall minimum of 20 sessions (or, in the Digital Delivery Model, episodes of engagement):

- minimum of 8 sessions (or, in the Digital Delivery Model, episodes of engagement) in the first 12 weeks – these must take place weekly for weeks 1 – 4 (or more frequently at the discretion of the Provider), and fortnightly in weeks 5 – 12 (or more frequently at the discretion of the Provider);
- minimum of 4 sessions (or, in the Digital Delivery Model, episodes of engagement) in weeks 13-18 – these must take place weekly for weeks 13 – 14 (or more frequently at the discretion of the Provider), and fortnightly in weeks 15 – 18 (or more frequently at the discretion of the Provider); and
- minimum of 8 sessions (or, in the Digital Delivery Model, episodes of engagement) in weeks 19 – 52 (these must occur monthly or more frequently at the discretion of the Provider)
- weekly sessions (or more frequently at the discretion of the Provider) during a rescue package after week 19 (i.e. during the Weight Maintenance Phase). The Provider expressly acknowledges that the all of the minimum requirements set out in the three preceding bullet points still comply even where a rescue package is put in place.

For the avoidance of doubt, week 1 begins on the first day of the TDR Phase.

The first session of (or, in the Digital Delivery Model, the first episode of engagement within) the TDR Phase must not be undertaken at the same time as the Individual Assessment.

The Provider's achievement of Milestone 1 will be subject to the relevant Service Achievement Criteria, as set out in Part 1 of Schedule 3C.

The planned participation of a Service User in the Service should be 52 weeks in total from the first day of the TDR Phase.

Additional contact outside of the minimum sessions (or, in the Digital Delivery Model, episodes of engagement) to further engage and support Service Users, to encourage retention is encouraged.

If a Service User has missed a session (or, in the Digital Delivery Model, an episode of engagement), additional contact to explore any barriers to engagement, re-engage them and cover missed content is encouraged.

The Provider should consider how it ensures that Service Users are given appropriate support which is aligned to their needs, preferences and individual circumstances, including cultural context.

Service Users should be made aware of the availability of peer support throughout the intervention. If the Service User accepts the offer of peer support, this should be facilitated by the Provider.

Sessions (or, in the Digital Delivery Model, episodes of engagement) must be offered at a range of times and days (and, for the Face-to-Face Delivery Models, venues) and where logistically possible in accessible locations to maximise access to (and therefore uptake of) the Service, particularly for those of working age, from ethnic minority groups and from more socially deprived backgrounds.

### **Planned Pauses**

If otherwise at risk of disengagement from the programme due to life circumstances or external factors, a planned pause by a Service User of up to 4 weeks can take place during any phase of the programme after the start of the TDR Phase. Where a pause is arranged, the Provider must share the details of the pause with the Service User's GP practice. If the Service User is not able to re-start the programme within 4 weeks of commencing the pause, the Service User should be discharged.

If, following discharge, the individual subsequently requests to re-start the programme, the Provider must inform the individual that they will need to be re-referred by their GP practice. If they had previously commenced the TDR Phase of the programme, they should be informed that they will not be accepted on to the programme until a period of 12 months has elapsed since the date that individual was discharged.

Where a Service User restarts the programme within 4 weeks after an agreed planned pause, the calculation of:

- that Service User's progression on the programme;
- the Milestone 2 Period; and
- the Milestone 3 Period,

must not take into account the period of the pause. For example, if a Service User commences an agreed planned pause at the end of week 14 and the pause lasts 2 weeks, on re-starting the programme, the Service User should be treated as starting week 15 of the programme.

Where a Service User commences an agreed planned pause during a rescue package, the rescue package is treated as having ended on the commencement of the pause.

### **3.2.7 Content of sessions/episodes of engagement**

The sessions (or, in the Digital Delivery Model, episodes of engagement) must support behaviour change, supporting compliance with TDR during the TDR Phase or during a rescue package. During the Food Re-introduction Phase and the Weight Maintenance Phase, the sessions (or, in the Digital Delivery Model, episodes of engagement) must provide information and practical tools on nutrition, behaviour change and weight management based on current national guidance as set out in section 4.1.

The content must consider the social and psychological support needed to support people to implement behaviour changes in environments which promote unhealthy behaviours.

The Provider must consider the relationship between the dietary treatment and the behavioural support as described in section 3.2.10 to ensure a coherent programme with logical progression.

For the Digital Delivery Model, the programme material should be designed to allow Service Users with different levels of knowledge and different approaches to learning to progress at different paces, with an appropriate reading age to optimise accessibility. This should include promoting self-directed learning.

The Provider must emphasise to Service Users the importance of continuing to attend for diabetes reviews at their GP practice, regardless of the outcome achieved with the Service.

### **3.2.8 Delivery of Sessions for the Face-to-Face Delivery Model**

Where the Provider delivers the Face-to-Face Delivery Model to a Service User, it must comply with this section.

The Provider's service model must ensure that all of the minimum sessions set out in section 3.2.6 are delivered one to one, face-to-face in-person between a Service User and the Provider if the Service User so chooses. The Provider must ensure that the opportunity to have all minimum sessions provided one to one face-to-face in-person is made expressly clear to all Service Users.

Where there is evidence that it will support delivery and participant engagement, and where the Service User:

- declines a one to one face-to-face in-person session; or
- cannot attend a scheduled one-to-one, face-to-face in-person session; or
- expresses a clear preference (unaffected by any influence of the Provider) for a session to be delivered in a manner other than one-to-one, face-to-face in-person,

a session may be delivered through other delivery mechanisms that involve Provider and Service User contact (options include, but are not limited to, telephone calls or video calls). Any such delivery through other delivery mechanisms must be driven by Service User choice. The Provider must not seek to influence the Service User's choice of delivery mechanism for any session. Where a Service User chooses or prefers one-to-one, face-to-face delivery, the Provider must not require a Service User to have a session delivered through other delivery mechanisms. Whichever mode of delivery is used, the requirements for monitoring and recording weight, blood glucose and, where applicable, blood pressure, remain (although it is acceptable for such readings to be obtained through self-measurement if a session is not delivered face-to-face in-person). Regardless of whether a Service User chooses that one or more sessions are delivered through other mechanisms, the Provider must ensure that for each Service User, the majority of the minimum sessions are delivered one-to-one, face-to-face and in-person.

Further individual contact, in addition to the minimum sessions set out in section 3.2.6, may also be included to enhance engagement and retention. Where requested by the Service User, the Provider should support attendance by a family member or carer.

Service Users should be offered a choice of dates and times for sessions to encourage attendance and also to offer the opportunity to catch up where they have missed a session. This choice should be available throughout a Service User's participation in the Service. The Provider should consider the extent to which the intervention is delivered in a logical progression.

References to delivery of a session "in-person" in this section 3.2.8 means the session will be delivered with the Service User and the Staff delivering the session being physically present at the same location. The Commissioner may notify the Provider that all or some of the sessions must be delivered remotely i.e. with the Services User and the Staff delivering the session not being physically present at the same location but having contact through a suitable online platform such as MS Teams, Zoom or Skype or other similar platform ("Remote Delivery").

At any time during the Contract Term, on one or more occasions the Commissioner may at its absolute discretion require the Provider to change the method of delivery of the sessions to Remote Delivery or back from Remote Delivery to the in-person delivery, as the case may be.

If the Commissioner requires the Provider to change the method of delivery of the sessions to Remote Delivery, the Commissioner will notify the Provider in writing and the Provider will change



the method of delivery of the sessions as soon as reasonably practicable following receipt of the notification and in any event in accordance with any timescales specified in the notification. If the Commissioner requires the Provider to change the method of delivery of the sessions from Remote Delivery to in-person delivery, it shall give the Provider notification in writing and the Provider will change the method of delivery of the sessions no later than 3 months following receipt of the notification.

The Provider will ensure that at all times during the Term it has all necessary premises and equipment available to provide in-person delivery and Remote Delivery of the sessions and it will provide Service Users with such equipment if necessary to change the method of delivery of the sessions to Remote Delivery.

If the Commissioner requires the Provider to change the method of delivery of the sessions, the Provider will notify all affected Service Users of the change in writing as soon as reasonably practicable, including details of how they can attend/access sessions under the new method of delivery. If a Service User's first session is held via in-person delivery and the Commissioner requires the Provider to change the method of delivery of the sessions to Remote Delivery, the Provider will ensure that all Service Users that are affected by the change are given the option to continue to attend/access the sessions via Remote Delivery even if the Commissioner subsequently requires the Provider to change back to in-person delivery. If a Service User's first session is held via Remote Delivery following a requirement from the Commissioner that the Provider changes the method of delivery, the Provider will continue to provide the Service to that Service User via Remote Delivery for the duration of that Service User's participation in the Service even if the Commissioner subsequently requires the Provider to change the method of delivery to in-person Delivery.

For the avoidance of doubt, the Provider's consent is not required for the Commissioner to require the Provider to change the method of delivery of the sessions and General Condition 13 does not apply to such a change.

The Service Price (as defined in Schedule 3C) will not be varied as a result of the Commissioner requiring the Provider to change the method of delivery of the sessions.

### **3.2.9 Delivery of episodes of engagement for the Digital Delivery Model**

The Provider must deliver the Digital Delivery Model in accordance with the following minimum requirements:

- The Provider must ensure that, in complying with the minimum engagement requirements detailed in section 3.2.6, there is contact between the Service User and Staff of the Provider at each episode of engagement.
- In addition to one-to-one episodes of engagement with the Service User, engagement may also be characterised by the interest and subjective experience of using the intervention, combined with the amount, frequency, duration and depth of usage. Such engagement might include: viewing materials, completing an education module or educational materials via a digital application or digital platform, completing a quiz, completing any active elements, use of tracking technology with associated data logged in the digital platform or application and, inputting self-monitoring data. For clarity, such engagement is in addition to one-to-one episodes of engagement and may not be used as a replacement for human coaching.
- Engagement would not include passive receipt of emails and other communications unless it could be demonstrated that these have been actively read through Service User feedback mechanisms embedded into the communication. Schedule 3C sets out the specific types of engagement methods that the Provider must ensure are used for payments to be claimed.
- The Provider must be able to demonstrate that their curricula/modules are designed to deliver engagement of Service Users for a minimum of twelve months.
- To ensure engagement is spread over twelve months, the Provider must ensure there are episodes of engagement at the frequency indicated in section 3.2.6. Schedule 3C (Local Prices) sets out the specific requirements that need to be met for payment.

- Subject to this section 3.2.9, access to the Service should be flexible to accommodate Service User preferences about accessing the Service at a time of their choosing and to work through content within the required frequency flexibly at their own pace.

### **3.2.10 Underpinning theory and development of approach**

The Provider should be explicit regarding the behavioural change theory and techniques that are being used, and the expected mechanism of action of their intervention (Evans et al, 2022<sup>1</sup>).

This must utilise a behaviour change framework which is evidence based such as those from the Public Health England Behaviour Change Guide: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/738214/adult\\_weight\\_management\\_changing\\_behaviour\\_techniques.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/738214/adult_weight_management_changing_behaviour_techniques.pdf).

The Provider must ensure that family, carer and/or household support is accommodated where this would be preferred by a Service User. The Provider should facilitate peer support for Service Users who have a preference for this.

The Provider must ensure that a multi-disciplinary team of health professionals or specialists relevant to the core components of the Service (i.e. Type 2 diabetes, behaviour change, weight loss, diet) is involved in development of the Service. These should include, as a minimum; a registered dietitian and registered health professional with specialist diabetes knowledge.

### **3.2.11 Training and Competencies for the Service**

The Provider will ensure that the Service is delivered by suitably trained and competent individuals who are trained in delivery of behaviour change. The Provider will specify the type and level of qualification, training and / or competence to be expected. The Provider needs to demonstrate that these qualifications will ensure that front-line Staff are trained to deliver interventions in line with [NICE PH49](#) (as set out in section 4.1) for overall behaviour change.

The Provider must ensure that all individuals involved in the delivery of the Service have sufficient and appropriate training and competencies required to deliver the actions and content of the Service, recognise individual needs and provide appropriate support including advice, techniques and signposting to other services. The Provider must manage confidential and sensitive personal identifiable data. This must include training in delivery of the Service. Training must be routinely monitored and updated as necessary, and suitable continued professional development strategies must be in place.

The Provider will ensure that all Staff adopt a person-centred, empathy-building approach in delivering the Service. This includes finding ways to help Service Users make changes by understanding their beliefs, needs and preferences and building their confidence.

The Provider must ensure that the Service is delivered in a way which is culturally sensitive to local populations, and flexible enough to meet the needs of Service Users with diverse needs. This includes adaptation of dietary advice and plans to the Service User's preferences and culinary traditions. Where reasonable and appropriate, the Provider will provide Services in languages to suit the needs of the local population.

Ideally staff delivering the Service will reflect the diversity of the population accessing the Service.

### **3.2.12 Clinical Training and Competencies for the Service**

There is not a requirement for health professionals to deliver content of sessions (or, in the Digital Delivery Model, episodes of engagement), nor be involved in sessions (or, in the Digital Delivery Model, episodes of engagement). In discussions about physical activity taking place during the Weight Maintenance Phase, it would be beneficial to involve a qualified physical activity instructor trained in behaviour change in the design of the Service.

All Staff required to undertake weight, blood pressure and finger-prick blood testing must be appropriately trained to do so.

<sup>1</sup> <https://pubmed.ncbi.nlm.nih.gov/36045887/>

All Staff delivering the Service must be trained to appropriately recognise adverse events, including those relating to blood pressure or blood glucose levels, and safely respond where able and appropriate to do. Those delivering the intervention are required to promptly seek advice from the Provider's appointed Medical Director. This will include a requirement to appropriately interpret results and feedback to GP Practices if there is concern.

The Provider must have a Medical Director, who is available at all times, relevant to the delivery of the Service, to advise Staff and provide guidance on appropriate courses of action particularly in the case of an adverse event. The Medical Director must be a registered medical practitioner within the meaning of Schedule 1 of the Interpretation Act 1978 and must have an MRCP or MRCGP.

It is the role of the Provider's Medical Director in relation to adverse events, to:

- Respond appropriately to all adverse events;
- Respond and give advice about non-serious adverse events and side effects; and
- Appropriately record all adverse events, liaise with the relevant Service Users' GP practices as appropriate, and notify the Commissioner within the next regular monthly report of adverse events and side effects (unless the Provider's Medical Director considers the individual circumstances of the event necessitate earlier reporting).

Staff must also have undergone information governance training and have confidentiality clauses in their contracts of employment.

The Provider acknowledges and agrees that the Service involves training, teaching, instruction, assistance, advice and guidance provided wholly or mainly for adults receiving healthcare. The Commissioner therefore considers the Service to be regulated activity for the purposes of regulations governing the use of Enhanced DBS & Barred List Checks and the Provider must carry out Enhanced DBS & Barred List Checks in respect of all members of Staff engaged in the Service who are eligible for such checks and must not engage any such person in the Service who is barred from working with vulnerable adults or is otherwise unsuitable for working with vulnerable adults. The Provider must ensure that any Sub-contractor is subject to similar obligations.

### 3.2.13 Weight Loss

It is anticipated that the majority of the weight loss will be attained during the TDR Phase.

The Provider must, following the TDR Phase or any further period of TDR, i.e. rescue packages, work with Service Users to assess their dietary intake and support planning of sustainable dietary changes, to achieve a healthy balanced diet as set out in the current national guidance. If the BMI of the Service User has decreased below 21 kg/m<sup>2</sup> in people from White ethnic groups or below 19 kg/m<sup>2</sup> in people from Black, Asian and other ethnic groups as set out in section 3.2.6 under the heading "TDR Phase" above, the Provider must not support further weight loss.

Following the TDR Phase or any further period of TDR, i.e. rescue packages, the Provider must design approaches to support Service Users to maintain a healthier weight in line with [NICE Guideline NG7](#).

### 3.2.14 Dietary content

Following the TDR Phase or any further period of TDR, i.e. rescue packages, the design and delivery of the curriculum must be underpinned by the UK Government dietary recommendations, acknowledging the findings of the Scientific Advisory Committee on Nutrition consultation (May 2021)<sup>2</sup>. The current recommendations are detailed in the Eat Well Guide<sup>3</sup>. The Eat Well Guide shows the proportions of the main food groups that form a healthy balanced diet. It promotes a diet high in fibre, fruit and vegetables and low in saturated fat, sugar and salt.

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<sup>2</sup> [SACN report: lower carbohydrate diets for type 2 diabetes - GOV.UK \(www.gov.uk\)](#)

<sup>3</sup> Eatwell Guide can be accessed at <https://www.nhs.uk/live-well/eat-well/the-eatwell-guide>

The Provider must support Service Users to achieve the Government's dietary recommendations, using dietary approaches that are evidence based and sustainable in the longer term.

The Commissioner may vary the requirements in this section 3.2.14 if there is a change in the national guidelines. For the avoidance of doubt, the Provider's consent is not required for such variations and General Condition 13 does not apply to such variations.

Service Users should be supported to set individualised weight maintenance goals following the TDR Phase which may include setting tailored achievable short, medium and long term dietary and physical activity goals which help them to achieve their aims.

Dietary advice should reflect the culinary traditions of the populations in which the Service is being provided wherever possible (information on the populations is set out in the Local Service Requirements in Appendix 2 of this Schedule 2A).

### **3.2.15 Physical activity content**

During the TDR Phase it is not recommended that additional physical activity is actively encouraged. However, following TDR, the Provider will support Service Users to undertake regular physical activity and aim to minimise or break-up extended periods of being sedentary, ultimately working towards achieving the UK Chief Medical Officer's physical activity recommendations: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/832868/uk-chief-medical-officers-physical-activity-guidelines.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/832868/uk-chief-medical-officers-physical-activity-guidelines.pdf).

The Provider will tailor the support provided as part of the Service to meet the needs, goals and capabilities of individual Service Users and care should be taken to set achievable goals in being active.

The Provider may incorporate into the Service, methods for self-monitoring to enable the Service User to capture individual-level change in weight, diet and physical activity. Methods may include the provision of, or integration with, wearable devices once the TDR Phase is complete.

The Provider must ensure that content of the Service is regularly reviewed and adjusted to stay up to date with government recommendations and new evidence.

### **3.2.16 Final Session/Episode of Engagement**

The "Final Session" (or, in the Digital Delivery Model, the "Final Episode of Engagement") is defined as the last session or episode of engagement delivered by the Provider as part of the planned Service (for those Service Users still attending or participating).

As part of the Final Session or Final Episode of Engagement, the Provider must conduct a post intervention assessment of weight, wellbeing, and achievement of individual goals for all Service Users who attend or participate. Arrangements for collection of Service User feedback / customer satisfaction survey should be agreed. Details of the data to be reported are provided in Schedule 6A.

The Provider must again ensure that links are made with local or national activities and services, in order to provide support for Service Users to continue with improvements made to dietary and physical activity behaviours and body weight.

The Provider must ensure that Service Users are reminded about key sources of information and advice, such as the NHS website.

The Provider should make available support and advice post intervention to Service Users to encourage the maintenance of improved lifestyles.

### **3.2.17 Service User measurements through the Programme**

Blood pressure

For Service Users who are prescribed medication which may lower blood pressure at the time of referral, blood pressure must be monitored by the Provider as follows;

- Blood pressure monitoring should be undertaken at every session (or, in the Digital Delivery Model, episode of engagement) with the Provider.
- Where the Face-to-Face Delivery Model is being delivered and a session is occurring face-to-face in-person, all required readings will be taken by the Provider at that face-to-face in-person session. If a session is being delivered through other mechanisms, all required readings may be obtained remotely e.g. through self-measurement
- For the Digital Delivery Model or where the Face-to-Face Delivery Model is subject to Remote Delivery, readings should be taken remotely using devices provided by the Provider, submitted to the Provider and reviewed as set out in this section.
- If Service Users go onto a rescue package the Provider must ensure weekly blood pressure monitoring over the duration of the rescue package.

The thresholds for action should be applied as follows:

- 89/59 mmHg or lower (systolic and/or diastolic) or postural symptoms – the Provider must contact the Service User's GP practice team. If symptoms are interfering with daily activities, same-day contact with the GP practice must be made (the Provider must contact the GP practice directly and the Service User must also be advised to contact their GP practice same-day);
- Between 90/60 and 159/99 mmHg – no additional action required, continue intervention;
- Between 160/100 and 179/119 mmHg (systolic and/or diastolic) over two sessions (or, in the Digital Delivery Model, two episodes of engagement) – the Provider must contact the Service User's GP practice;
- 180/120 mmHg or higher (systolic and/or diastolic) – there must be same-day contact with the Service User's GP practice (the Provider should contact the GP practice directly and the Service User must also be advised to contact their GP practice same-day);
- For avoidance of doubt, if a blood pressure reading could fit into two of the categories described above (such as 181/118 mmHg), action should be taken in line with the category prompting the most rapid response (in this case, same-day contact with the GP practice).

For the Digital Delivery Model, and any sessions being delivered as part of the Face-to-Face Delivery Model but which are not being delivered in-person (whether due to Service User choice or Remote Delivery required by the commissioner), blood pressure measurement may be arranged at venues or services nearby and convenient to Service Users or self-measurement may be used (with relevant equipment, training and support provided to the Service User by the Provider at the Provider's cost).

The Provider must use a validated device for the type of testing that they propose, and ensure that their workforce has received appropriate training to use the devices as specified, providing quality measurements. Guidance on appropriate monitors can be found here <https://bihsoc.org/bp-monitors/>.

## **Weight**

Weight measurements must be taken at every session.

Where the Face-to-Face Delivery Model is being delivered and a session is occurring face-to-face in-person, all required readings will be taken by the Provider at that face-to-face in-person session.

For the Digital Delivery Model, and any sessions being delivered as part of the Face-to-Face Delivery Model but which are not being delivered in-person (whether due to Service User choice or Remote Delivery required by the commissioner), all required readings may be obtained remotely e.g. through self-measurement.

The baseline weight and height measurement should be recorded by the Provider at the first session (or, in the Digital Delivery Model, episode of engagement) of the TDR Phase.

BMI will be calculated at baseline and every time a weight measurement is taken. As set out in section 3.2.6, TDR should be stopped, with no further advice directed at weight loss, if BMI falls below 21kg/m<sup>2</sup> in people from White ethnic groups or below 19kg/m<sup>2</sup> in people from Black, Asian and other ethnic groups.

Data collection of weight measurements in face-to-face in-person sessions must be taken using appropriately calibrated scales (see PHE standard evaluation framework for weight management interventions for details of measurement of height and weight: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/685545/SEF\\_weight\\_management\\_interventions.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/685545/SEF_weight_management_interventions.pdf)).

Scales used to measure weight where Face-to-Face Delivery Models are being used should meet Class III scales for levels of accuracy as per UK weighing federation guidance): <http://www.ukwf.org.uk/res/medicalguidancenotes.pdf>.

For the Digital Delivery Model, and where a session is being delivered as part of the Face-to-Face Delivery Model but which is not being delivered in-person (whether due to Service User choice or Remote Delivery required by the commissioner), the Provider will provide at its own cost scales to each Service User and home scale readings must be shared by Service Users with the Provider. Measurements must be taken at all sessions (or, in the Digital Delivery Model, episodes of engagement) as specified in this Service Specification, on the same device consistently (as appropriate). For all devices provided to Service Users by the Provider, the Provider must ensure that the device adheres to the error margins for Class IV scales (set out in Table 1 of the UKWF Guidance). The Commissioner acknowledges there may be limited options on the market for certified Class IV scales (particularly digital scales that are certified Class IV in the UK), so confirmation from the manufacturer that the scales adhere to the error margins for Class IV scales (set out in Table 1 of the UKWF Guidance) is acceptable, in place of the official certification.

If Service Users go on a rescue package at any stage during the Service, the Provider must ensure weekly weight measurement recording and reporting for the duration of the rescue package.

#### Blood glucose testing

For all Service Users, finger prick capillary blood glucose testing should be monitored by the Provider as follows;

- Finger prick capillary blood glucose testing should be undertaken at every session with the Provider;
- Where the Face-to-Face Delivery Model is being used and a session is occurring face-to-face in-person, all required readings will be taken by the Provider at the relevant session. For the Digital Delivery Model, and where a session is being delivered as part of the Face-to-Face Delivery Model but which is not being delivered in-person (whether due to Service User choice or Remote Delivery required by the commissioner), all required readings will be submitted by the Service User to the Provider and reviewed as set out in this section;
- If Service Users go onto a rescue package the Provider must ensure weekly blood glucose monitoring over the duration of the rescue package.

The thresholds for action should be applied as follows:

- Under 15 mmol/l – no additional action required, continue intervention;
- Between 15.0 - 19.9 mmol/l over 2 Sessions – the Provider must contact the Service User's GP practice;
- 20.0 mmol/l or higher – there must be same-day contact with the Service User's GP practice team (the Provider must contact the GP practice directly and the Service User must also be advised to contact their GP practice same-day).

Finger prick blood glucose testing may be arranged at venues or services nearby and convenient to Service Users or self-measurement may be used for the Digital Delivery Model, and where a session is being delivered as part of the Face-to-Face Delivery Model but which is not being delivered face-to-face in-person (whether due to Service User choice or Remote Delivery required by the commissioner), with relevant equipment, training and support provided to the Service User by the Provider at the Provider's cost.

When selecting blood glucose meters the Provider should ensure that the selected meter meets current International Organization for Standardization (ISO) standards for blood glucose meters



(ISO15197)<sup>4</sup> and that choice is aligned with locally agreed provision of blood glucose meters on the NHS.

The CQC's guidance on the diagnostic and screening procedure regulated activity confirms that non-ambulatory blood pressure monitoring and blood tests carried out by means of a pin prick test are excluded from the registration requirements for this regulated activity. However, the Provider must satisfy itself as to whether CQC registration is required for any action that it undertakes.

### 3.2.18 Discharge from the Service

The Service User is "Discharged" from the Service in the following circumstances:

- If, after the Provider contacts an individual following referral, the individual does not respond to the Provider after one calendar month from referral provided that the Provider has made a minimum of three attempts to contact the individual, and used various communications channels as set out in section 3.2.4 above;
- If, after the Provider contacts an individual following referral, the individual indicates that they do not accept the Service;
- If, after the Provider contacts an individual following referral, the individual indicates that they accept the Service, and do not complete an Individual Assessment within 90 days of referral;
- If, after the Service User has accepted the Service but fails to attend or participate in a scheduled and agreed Individual Assessment, an Individual Assessment has not been completed within one calendar month of the date the Service User failed to attend or participate in the scheduled and agreed Individual Assessment;
- If, following an Individual Assessment the individual:
  - does not attend or participate in a first session (or, in the Digital Delivery Model, episode of engagement) where the Provider has offered the session (or, in the Digital Delivery Model, episode of engagement) on three separate occasions at times (and for the Face-to-Face Delivery Model, venues) suitable to the individual; or
  - does not attend the first session (or, in the Digital Delivery Model, episode of engagement) within 90 days of the Individual Assessment;
- If, during the TDR Phase, it is established that the Service User is not complying, or unable to comply, with the requirements of the Service;
- If, whilst participating in the Service, an adverse or concurrent event occurs of sufficient severity that it would no longer be appropriate for the Service User to continue on the Service;
- If a Service User becomes pregnant whilst participating in the Service, the Service User should be discharged from the Service to the care of her GP practice. It must be made clear to pregnant women that weight loss or dieting during pregnancy is not advised;
- When a Service User informs the Provider they no longer wish to participate in the Service;
- If, during the first 2 weeks of the TDR Phase, it is established that a Service User cannot tolerate the TDR products;
- If, during the first four weeks of the TDR Phase, a Service User misses a session (or, in the Digital Delivery Model, episode of engagement) (or there is no recorded engagement for one week) without prior notification to the Provider and the Service User does not make contact within one week; or the Service User is not successfully contacted by the Provider within one week and the Provider has made a minimum of three attempts to contact the

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<sup>4</sup> <https://www.iso.org/standard/54976.html>

Service User using at least two of the following means of communication: letter, phone call, text message or email;

- If, during the TDR Phase after the first four weeks or during a rescue package, a Service User misses a session (or, in the Digital Delivery Model, episode of engagement) (or there is no recorded engagement for two weeks) without prior notification to the Provider and the Service User does not make contact within two weeks, or is not successfully contacted by the Provider within two weeks following a minimum of three attempts to contact the Service User using at least two of the following means of communication: letter, phone call, text message or email;
- If, after planned pause agreed in accordance with section 3.2.6, a Service User does not re-start the programme within 4 weeks of commencing the pause;
- If, during the Food Reintroduction and Weight Maintenance Phases, if a Service User misses a session (or, in the Digital Delivery Model, episode of engagement) (or there is no recorded engagement for four weeks) without prior notification to the Provider and the Service User does not make contact within four weeks, or is not successfully contacted by the Provider within four weeks following a minimum of three attempts to contact the Service User using at least two of the following means of communication: letter, phone call, text message or email;
- If a Service User does not submit measurements of the same type (weight, blood glucose, or blood pressure if applicable) at two consecutive sessions set out in section 3.2.17 where the Service User is required to submit them and the Provider has made a minimum of three attempts to contact the Service User to obtain each such measurement using at least two of the following means of communication: letter, phone call, text message or email;
- On completion of the Final Session or Final Episode of Engagement (or once the Final Session or Final Episode of Engagement has been delivered). Once the Final Session or Final Episode of Engagement is completed then the Service User is discharged automatically regardless of the number (or percentage) of sessions attended or episodes of engagement participated in.

The Provider must notify the Service User's GP practice that the Service User has been discharged. The length of time the Service User participated, the stage of the intervention reached, and the initial and most recent weight measurements should be communicated, as well as the reason for discharge. If the Service User has been discharged during the TDR Phase and any medication changes were made on the first day of TDR, the GP practice must be asked to arrange review to consider restarting medication using the template letters provided by the Commissioner.

Where an individual has previously started TDR and has subsequently been discharged from the programme for any reason, the Provider will not accept a re-referral of that individual until at least 12 months have elapsed since the date they were previously discharged.

### **Discharge Requirements**

If a Service User had started the TDR Phase but is discharged before the TDR Phase is completed, the Provider must provide the Service User and the GP practice with a letter of discharge in accordance with the template letters provided by the Commissioner. Unless otherwise specified in these template letters, if any medication were stopped on the first day of TDR, the letter should advise the Service User to make contact with their GP practice within two Operational Days to arrange a review to discuss the potential need to restart medication (determination of the required urgency of such a review will be up to the GP practice), or if no medications were stopped on the first day of TDR, the letter should advise the Service User to make contact with their GP practice within 4 weeks for a routine review. Similarly, the letter of discharge to the GP practice must reflect this advice.

Unless otherwise specified in the template letters, if discharge occurs once the TDR Phase has been completed, the letter of discharge must advise the Service User to make contact with their GP practice within 4 weeks for consideration of a repeat blood tests and a routine review. Similarly, the



letter of discharge to the GP practice must advise the GP practice to consider repeat blood tests and a routine review.

The Provider must comply with any template letters or discharge communication content that the Commissioner notifies the Provider must be used.

The Provider must comply with relevant clinical codes associated with data items and include clinical codes in all notifications as specified by the Commissioner under the Contract.

### **3.2.19 Links to other services**

The Provider must ensure that links are made with existing local networks and partnerships throughout the development and delivery of the Service. This could include, for example, leisure and public health services, departments within Local Authorities, the NHS website, and local "Exercise on Referral" schemes.

### **3.3 Marketing of the Service**

The Provider must undertake marketing and promotional activity in conjunction with the local health system to advertise the existence of the Service, with a view to raising awareness of the eligibility criteria and the availability and benefits of the Service amongst local GP Practices and to people in the geographical area covered by the Contract and eligible for the service who may benefit from participating in the NHS T2DR Programme. Any marketing or promotional activity must be designed to target groups in the community which are currently less likely to access services and encourage them to find out more about and attend or participate in the Service.

In marketing the Service, the Provider must conform to any guidelines on social marketing of the Service under the Contract, for example to ensure alignment of messaging with any wider social marketing campaigns being undertaken in relation to diabetes, or health promotion more generally. This includes using any branding guidelines developed by the Commissioner specifically for this Service.

Providers must NOT use personal information provided to them by GP practices to target individuals directly.

### **3.4 Intellectual Property**

For the avoidance of doubt, notwithstanding General Condition 1.2, the Parties expressly agree that this section 3.4 shall take precedence over General Condition 22 in respect of Intellectual Property.

Except as set out expressly in this Contract, no Party will acquire the IPR of the other Party.

The Provider grants the Commissioner a fully paid-up non-exclusive licence to use Provider IPR for the purposes of the exercise of its functions and obtaining the full benefit of the Services under this Contract, which will include the dissemination of best practice to commissioners and providers of health and social care services.

The Commissioner grants the Provider a fully paid-up non-exclusive licence to use Commissioner IPR under this Contract for the sole purpose of providing the Services.

In the event that the Provider or the Commissioner at any time devise, discover or acquire rights in any Improvement it or they must promptly notify the owner of the IPR to which that Improvement relates giving full details of the Improvement and whatever information and explanations as that Party may reasonably require to be able to use the Improvement effectively and must assign to that Party all rights and title in any such Improvement without charge.

Any IPR created by the Commissioner in the exercise of its licence rights under this Contract will be owned by the Commissioner.

The Provider must disclose all documents and information concerning the development of Best Practice IPR to the Commissioner at Review Meetings and must grant the Commissioner a fully paid-up, non-exclusive perpetual licence to use Best Practice IPR for the purpose of the exercise of its functions together with the right to grant sub-licences to Public Health England and any Participating Commissioner for the purpose of the exercise of their respective functions.

“Best Practice IPR” in this section 3.4 means any IPR developed by the Provider including Improvements to such IPR in connection with or as a result of the Services.

“Improvement” in this section 3.4 means any improvement, enhancement or modification to Commissioner IPR, Provider IPR or Best Practice IPR (as the case may be) which cannot be used independently of such IPR.

“IPR” in this section 3.4 means inventions, copyright, patents, database right, domain names, trade marks, module names, rights in computer software, database rights, rights in get-up, goodwill and the right to sue for passing off, designs and confidential know-how and any similar rights anywhere in the world whether registered or not, including applications and the right to apply for any such rights.

“Participating Commissioner” in this section 3.4 means a clinical commissioning group or local authority in relation to whose geographical area the Services are delivered.

“Provider IPR” in this section 3.4 means any IPR owned by or licensed to the Provider (other than by the Commissioner) that will be used by the Provider in the delivery of the Services (as set out in Appendix 3 of this Schedule 2A), including Improvements to such IPR.

The Provider shall ensure and procure that the availability, provision and use of the Service and the performance of the Provider's responsibilities and obligations hereunder shall not infringe any Intellectual Property Rights of any third party.

The Provider shall during and after the Contract Term indemnify the Commissioner against all Losses incurred by, awarded against or agreed to be paid by the Commissioner (whether before or after the making of the demand pursuant to the indemnity hereunder) arising from an IPR Claim. An IPR Claim is defined as any claim of infringement or alleged or threatened infringement by a third party (including the defence of such infringement or alleged or threatened infringement) of any IPR, used to provide the Services or as otherwise provided and/or licensed by the Provider (or to which the Provider has provided access) to the Commissioner in the fulfilment of its obligations under this Contract.

If an IPR Claim is made, or the Provider anticipates that an IPR Claim might be made, the Provider may, at its own expense and sole option, either:

- procure for the Commissioner the right to continue using the relevant IPR which is subject to the IPR Claim; or
- replace or modify the relevant deliverable with non-infringing substitutes provided that:
  - the performance and functionality of the replaced or modified deliverable is at least equivalent to the performance and functionality of the original deliverable; and
  - there is no additional cost to the Commissioner.

If the Provider elects to procure a licence or to modify or replace a deliverable pursuant to the provision above but this has not avoided or resolved the IPR Claim, then:

- the Commissioner may terminate this Contract by written notice with immediate effect; and
- without prejudice to the indemnity set out above, the Provider shall be liable for all reasonable and unavoidable costs of the substitute deliverables and/or services including the additional costs of procuring, implementing and maintaining the substitute deliverables.

### 3.5 Cyber Essentials

The Provider has and will maintain certification under the HM Government Cyber Essentials Scheme (basic level) until such time as the Provider obtains Cyber Essentials Plus certification in accordance with the provision below.

The Provider shall, as soon as is reasonably practicable after the Services Commencement Date, obtain certification under the HM Government Cyber Essentials Scheme to the level of Cyber Essentials Plus and maintain such certification for the Contract Term.

### 3.6 Digital Technology Assessment Criteria

The Provider must ensure that the Service, when provided via the Digital Delivery Model complies with the requirements of the Digital Technology Assessment Criteria ("**DTAC**") and ensure that the Service is updated if requirements of the DTAC are updated.

### 3.7 Government Digital Service Technology Code of Practice

The Provider must ensure that the Service adheres to the requirements of the Government Digital Service Technology Code of Practice, which is currently available at:

<https://www.gov.uk/government/publications/technology-code-of-practice/technology-code-of-practice>

### 3.8 Identity Verification and Authentication Standard for Digital Health and Care Services

If the Provider's Digital Service is by its nature a service to which NHS Digital's "Identity Verification and Authentication Standard for Digital Health and Care Services" applies, then the Provider is required to ensure it adheres to this standard. Please refer to the Standard for applicability:

<https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb3051-identity-verification-and-authentication-standard-for-digital-health-and-care-services>.

The Provider agrees to provide evidence of adherence to the standard to the Commissioner on request.

### 3.9 Information Governance

The Provider will submit the "Data Output Specification" document in Schedule 6A to the commissioning support service specified by the Commissioner and in the manner specified by the Commissioner.

The Provider will invite all individuals they have contacted following referral and all Service Users to agree be contacted for the purpose of service evaluation and record their consent where given. The Commissioner will specify this proportion of Service Users and also the timing and manner of the invitation.

The Provider will respect any request by a Service User not to disclose information that identifies them in the documents indicated above.

For the avoidance of doubt, the requirements above are in addition to the information governance requirements set out elsewhere in this Contract.

### 3.10 Additional Service Delivery Requirements

The Provider must:

- provide the Service in the following geographical area – **Bedfordshire, Luton and Milton Keynes ICS**
- ensure that the number of Service Users who achieve Milestone 1 (as defined in Schedule 3C) does not exceed 500 during the Contract Term. This number is the "Intervention Cap" for the purposes of Schedule 3C;
- work with the local health system to agree and implement a strategy for managing demand within the Intervention Cap;
- ensure that no Service User is invited to participate in the Service after a period of two years has elapsed since the Effective Date. This period is the "Intervention Period" for the purposes of Schedule 3C;

- actively monitor and report to the Commissioner and local health systems, the number of Service Users who achieve Milestone 1 on the Service throughout the Contract Term; and
- notify the Commissioner as soon as reasonably practicable where the number of Service Users achieving Milestone 1 (as defined in Schedule 3C) is predicted to exceed the Intervention Cap.

The Commissioner may at its discretion either:

- vary the Intervention Cap and/or the Intervention Period; and/or
- notify the Provider that it will not vary the Intervention Cap and/or the Intervention Period.

Where the Commissioner varies the Intervention Cap and/or Intervention Period it will notify the Provider and the Provider shall comply with the variation.

For the avoidance of doubt:

- the Provider's consent is not required for such variations and General Condition 13 does not apply to such variations; and
- varying the figures for the purpose of this section 3.10 includes increasing or decreasing the relevant figure.

The Provider will not be paid for the Service provided to any additional Service Users:

- invited to participate in the Service once the Intervention Cap has been reached in accordance with paragraph 2 of Part 1 of Schedule 3C; and/or
- invited to participate in the Service once the Intervention Period has expired in accordance with paragraph 2 of Part 1 of Schedule 3C.

The Contract Term will be the period from the Effective Date to the day after which the Provider submits the data submission for the last Service User being provided with the Service who completed the Final Session or Final Episode of Engagement or other such day as agreed in writing between the Parties.

### 3.11 Transition

Prior to expiry or termination of this Contract, a new provider may be preparing to deliver similar services under a contract that the Commissioner has newly put in place. In such a situation, there will be a period during which the Provider is winding down its delivery of the Service under this Contract (i.e. it will not be accepting any new referrals to its service) and a new provider is commencing delivery of their service.

This period is referred to as a "Transition Period". This section 3.11 sets out obligations on the Provider who is winding down its delivery of the Service. During a Transition Period the Provider will comply with the relevant obligations set out below.

The aim during the Transition Period is that:

- General Practice engagement is maintained and a steady flow of referrals continues;
- A high quality of service is provided to service users regardless of which provider's service they are referred to, or enrolled on; and
- There is an orderly wind down by the Provider and a smooth mobilisation and commencement of delivery of the service by the incoming provider.

Subject to the other requirements of this section 3.11, the Provider is responsible for delivering the Service to all Service Users who have been invited to participate as defined in this Contract, within the Intervention Cap and the Intervention Period specified in this Contract. The Provider must

maintain high levels of engagement with Service Users throughout the Transition Period, and ensure that there is a sustainable workforce and delivery model to manage the Transition Period.

During the Transition Period, there will likely be individuals who have been referred to the Provider but who have not yet been invited to participate prior to the Intervention Period expiring. Such individuals will be transferred, in compliance with Data Protection Legislation, by the Provider to the incoming provider. Individuals who have not achieved (or who are unlikely to achieve, in the opinion of the Provider) Milestone 1 by the 2 month anniversary of the expiry of the Intervention Period will also be transferred by the Provider to the incoming provider unless those individuals will achieve Milestone 1 on the next submission of the Data Output Specification to the Commissioner following the 2 month anniversary.

The Provider is responsible for complying with relevant Data Protection Legislation and the duty of confidentiality throughout the transfer process.

The Provider shall provide to the incoming provider details on waiting lists of individuals and current session delivery locations to support sustainability of service delivery and the Provider is required to attend joint planning meetings with the incoming provider throughout the Transition Period to support operational delivery. The Provider will continue to provide data to the local health system and will provide an operational point of contact until all Service Users being provided with the Service have either completed participation in the Service or have been discharged.

### **3.12 Review meetings**

Review meetings between the Provider and the Commissioner in accordance with General Condition 8 of this Contract shall be conducted on behalf of the Commissioner by any person nominated by the Commissioner to act on its behalf. References to the "Commissioner" in the context of Review Meetings shall be construed accordingly.

The Provider will attend monthly meetings (whether in person or remotely) with the Commissioner Representative to discuss progress of the delivery of the Services and any key issues arising. The matters to be discussed at such meetings shall be as agreed between the Provider and the Commissioner Representative. Such meetings shall be held in addition to Review Meetings (which shall be held on a quarterly basis). The Provider will agree a written record of the key outputs from such meetings with the Commissioner Representative and provide a copy of such record to the Commissioner Representative within one month of the relevant meeting.

Unless agreed otherwise by the Parties, at least one week in advance of these meetings the Provider will deliver to the Commissioner the performance reports detailed in Schedule 6A, in the format described.

The Provider will attend monthly meetings (as a minimum; whether in person or remotely) with local lead partner organisations, in whose areas the Services are delivered, to review progress and address any specific local issues relating to the delivery of the Services. These may include the rate of referrals to the Services, uptake rates, issues with the referral process or service delivery, and equity of access, uptake, retention and outcomes (particularly in relation to inequity by ethnicity and socioeconomic deprivation), and any other matters as either the Provider or the relevant local partner organisations considers relevant to the Services. Appropriate analysis and reporting of performance relating to the programme in the local health system should be made available, with particular focus on exploring and addressing inequalities. The Provider will agree a written record of the key outputs from such meetings with the local partner organisations and provide a copy of such record to the Commissioner Representative within one month of the relevant meeting. Such meeting records will be reviewed at Review Meetings between the Provider and the Commissioner.

At least one week in advance of these meetings, the Provider will deliver to the local lead partner, the data and performance reports detailed in Schedule 6A, in the format described.

### **3.13 Evaluation and Quality Assurance**

The Provider will participate fully in any Quality Assurance processes defined by the Commissioner and co-operate in undertaking ad-hoc audits and reviews as requested by commissioners in a timely manner. This will include the submission to commissioners of:

- Agreed data and reports from external quality assurance schemes
- Self-assessment questionnaires / tools and associated evidence.

The Provider will also participate in evaluations of the Service commissioned by or approved by the Commissioner.

The Provider must ensure that a process is in place to obtain Service User feedback, such as through use of the Family and Friends Test and a system is in place for how that feedback is considered and actioned.

#### 4. Applicable Service Standards

##### 4.1 Applicable national standards (e.g. NICE)

The Provider will deliver the Service in accordance with all relevant clinical guidelines and other guidance and publications published nationally, in particular:

- The Provider will deliver the Service in accordance with all relevant clinical guidelines and other guidance and publications published nationally, in particular:
  - NICE NG 28 Type 2 Diabetes in Adults: Management (2022)
  - NICE NG 7 Preventing excess weight gain
  - NICE PH 42 Obesity: working with local communities (2012)
  - NICE PH 6 Behaviour change: the principles for effective interventions (2007)
  - NICE PH 49 Behaviour change: individual approaches (2014)
  - NICE PH 44 Physical activity: brief advice in primary care (2012)
  - NICE PH 41 Physical activity: walking and cycling (2013)
  - NICE CG 43 Obesity: Guidance on the prevention of overweight and obesity in adults and children (2006 and updated 2015)
  - NICE PH 53 Managing overweight and obesity in adults – lifestyle weight management services (2014)
  - NICE PH 46 BMI: preventing ill health and premature death in black, Asian and other minority ethnic groups (2013)
  - Eatwell Guide (2016)
  - NICE NG 183 Behaviour change: digital and mobile health interventions (2020)

#### 5. Applicable quality requirements

##### 5.1 Applicable Quality Requirements

The Quality Requirements applicable to the Service are set out in Schedule 4.

##### 5.2 Equity and access

In the delivery of the Service the Provider must comply with the obligations placed on the Commissioner by section 13G of the NHS Act 2006 (due regard to the need to reduce health inequalities) and section 149 of the Equality Act 2010 as if those obligations applied directly to the Provider;

The Provider must promptly provide such co-operation to the Commissioner as the Commissioner reasonably requests regarding the Commissioner's discharge of its duties under section 13G of the NHS Act 2006 and section 149 of the Equality Act 2010; and

The Provider will complete an annual Equality and Health Inequalities Impact Assessment (E&HIIA) and action plan to challenge discrimination, promote equality, respect Service Users' human rights and to reduce health inequalities in access to services and outcomes. The E&HIIA and action plan shall be provided to the Commissioner on the Effective Date and each anniversary of the Effective Date. Progress against the action plan will be reported by the Provider to the Commissioner on a Quarterly basis at the relevant Review Meeting.

The Provider must at all times adhere to all relevant health and safety and security Law in providing the Services.

**SCHEDULE 2 THE SERVICES**

**A. Service Specifications**

**Appendix 1**

**Tender Response Document**

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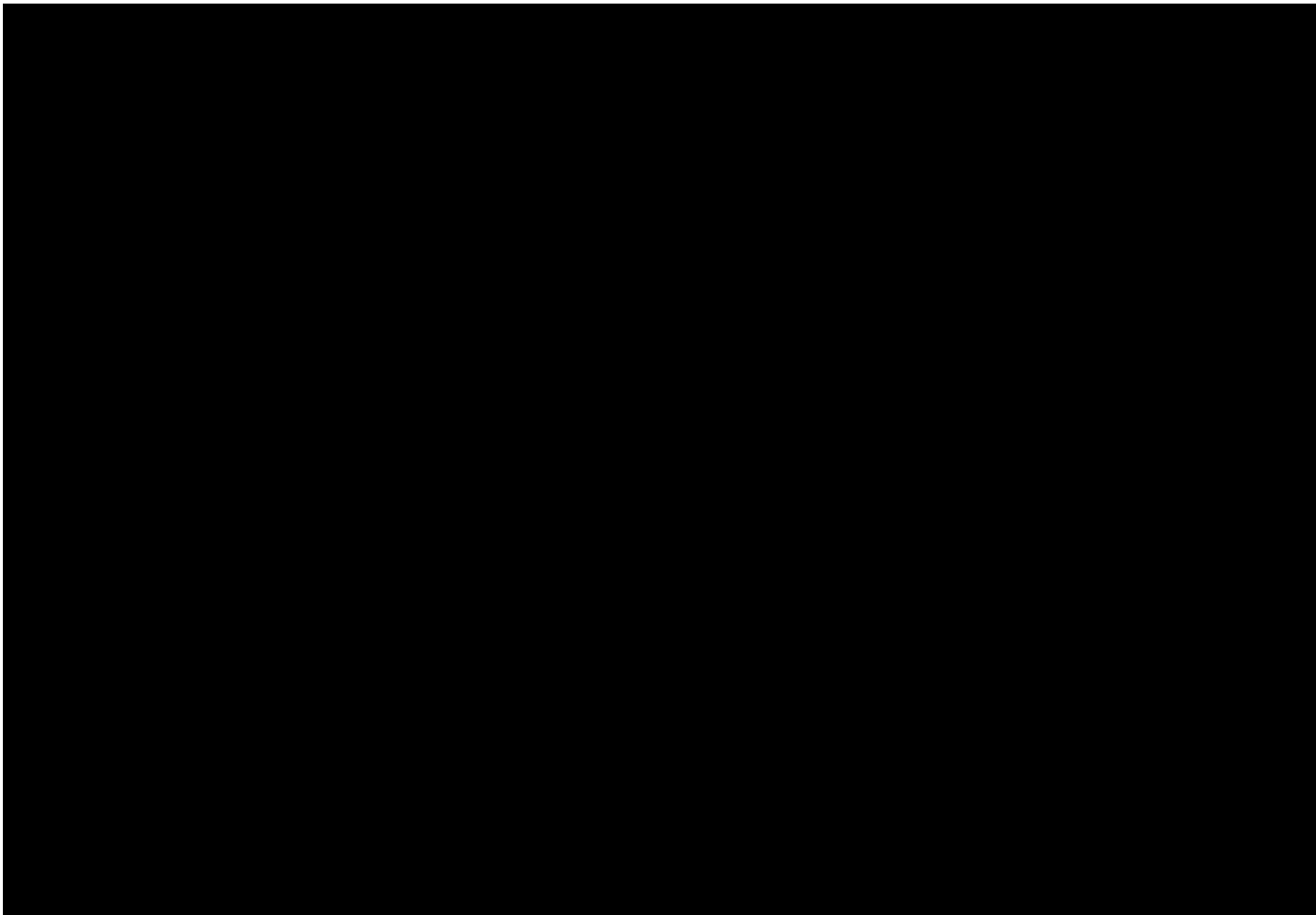
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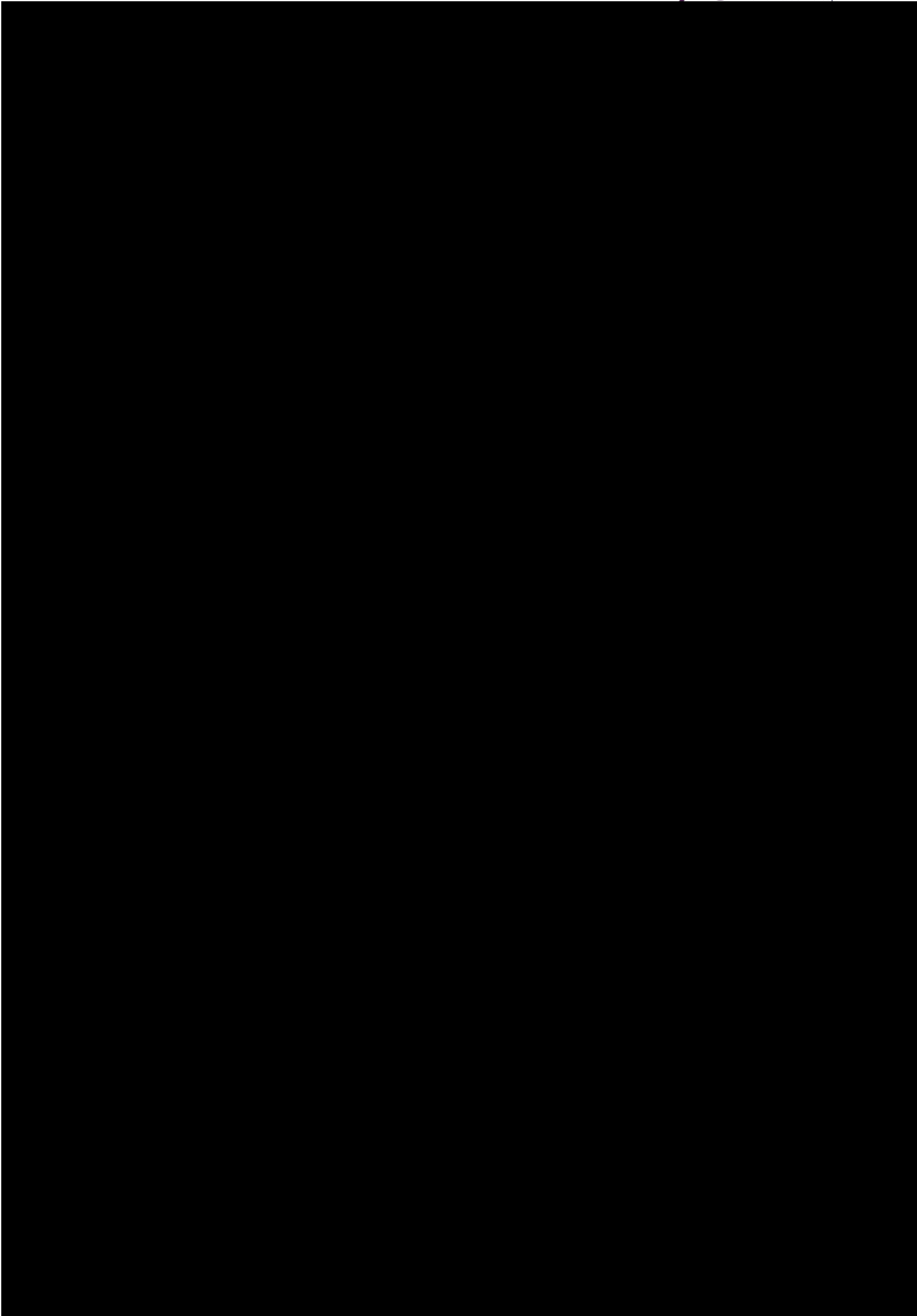
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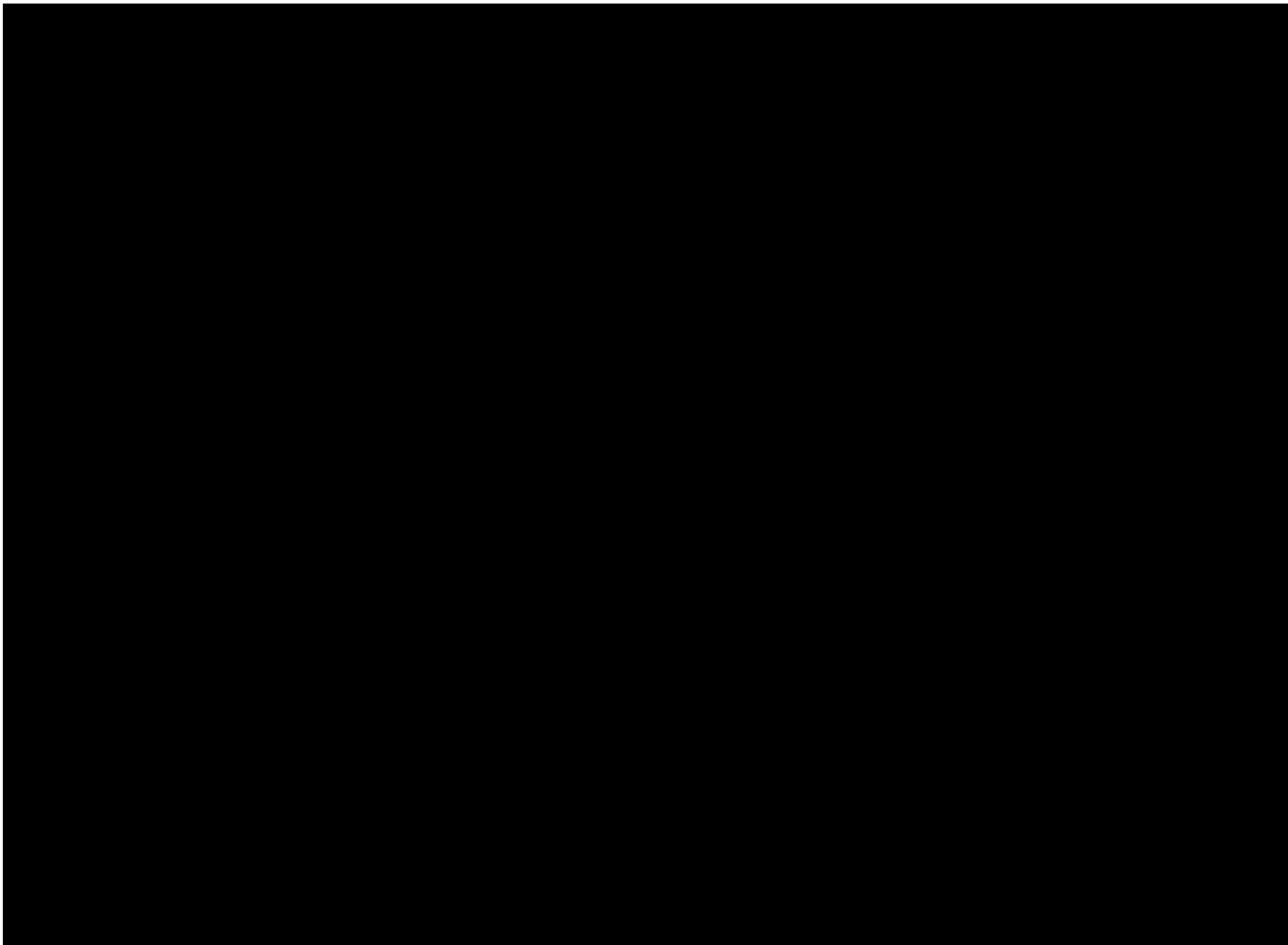
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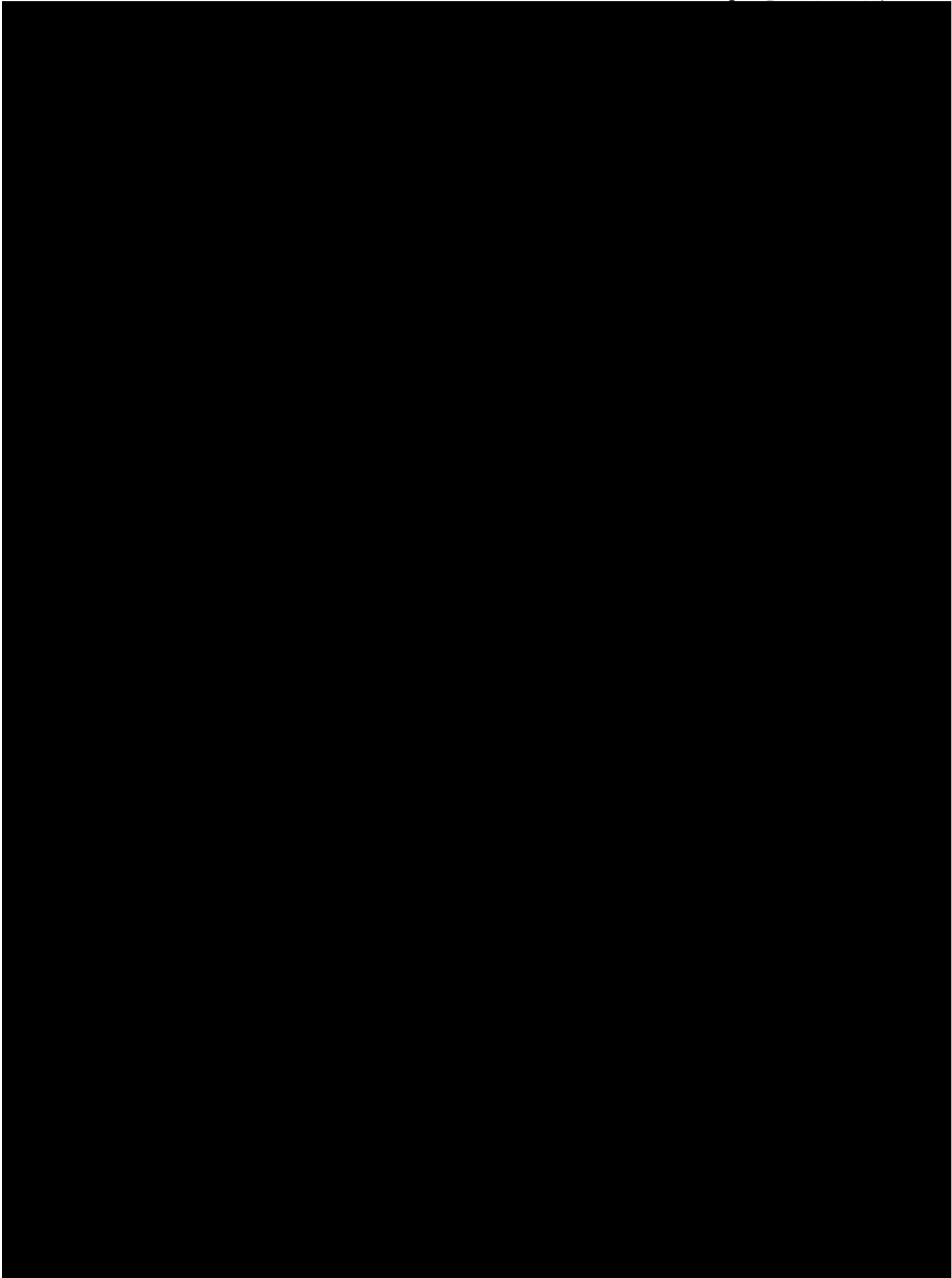
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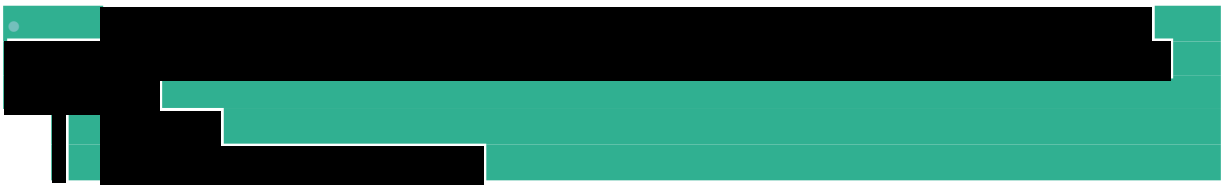
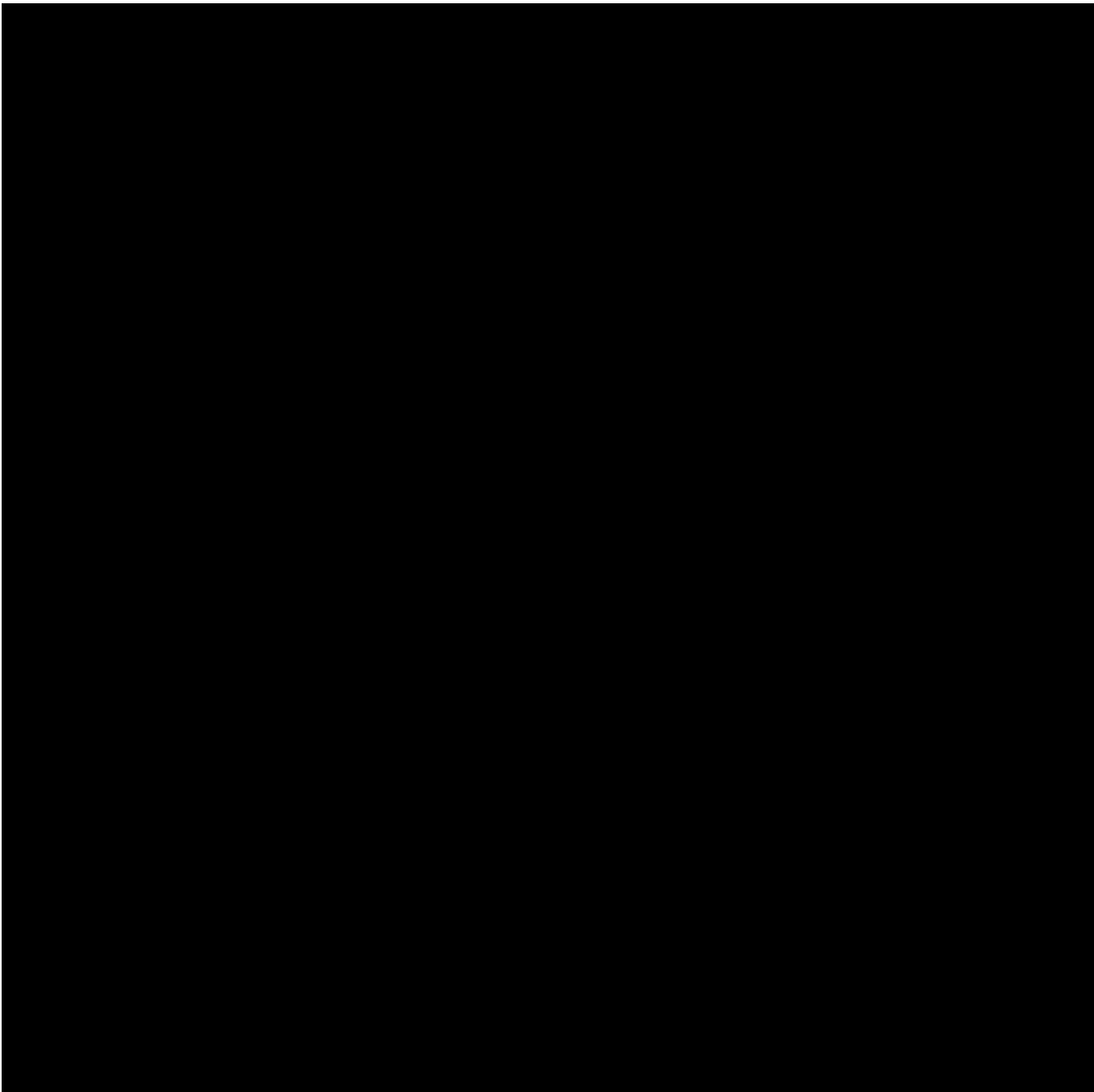
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Figure 1. The effect of the number of trials on the number of correct responses. The number of correct responses was significantly higher for the 10 trials condition than for the 5 trials condition. Error bars represent the standard error of the mean.

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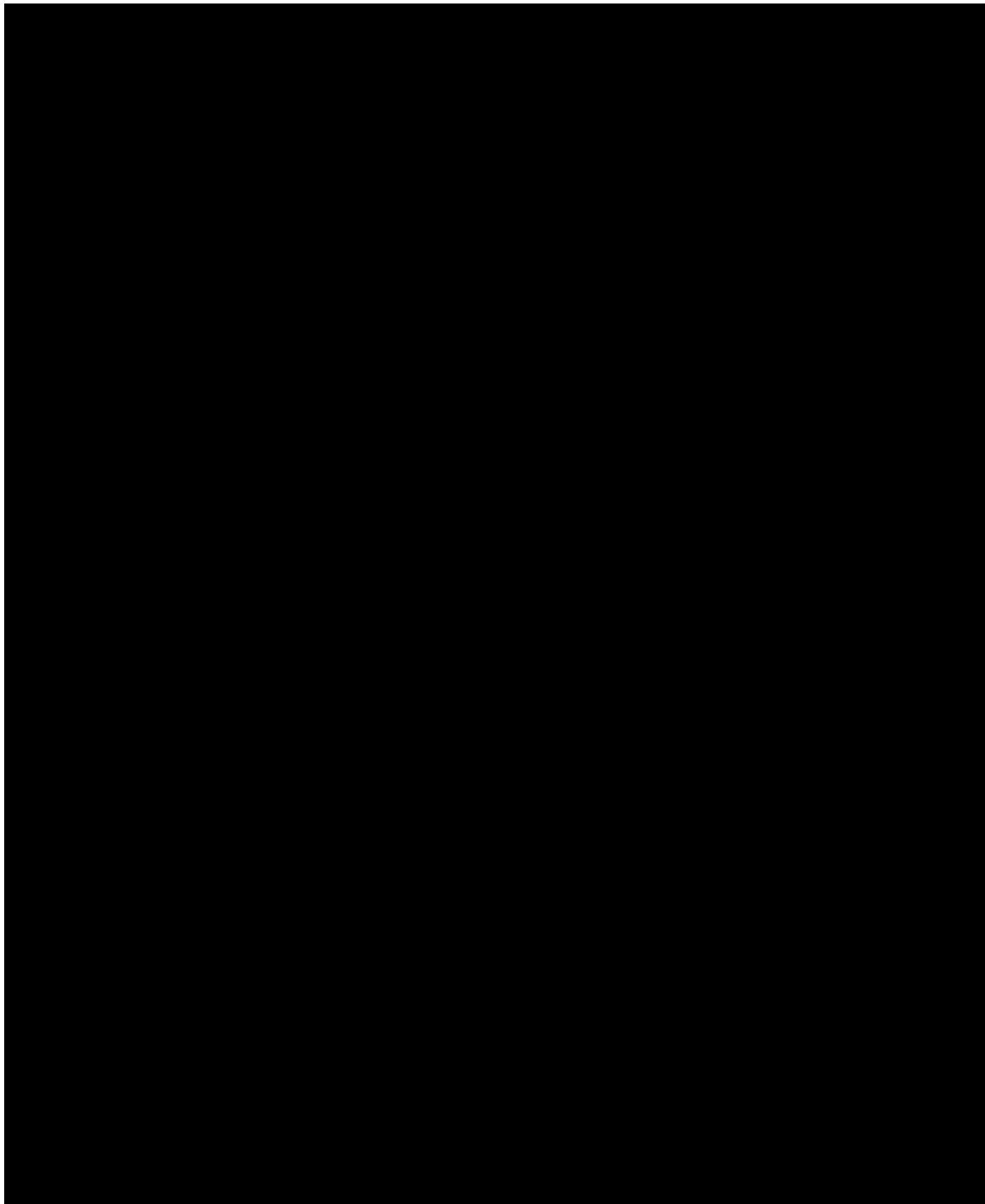
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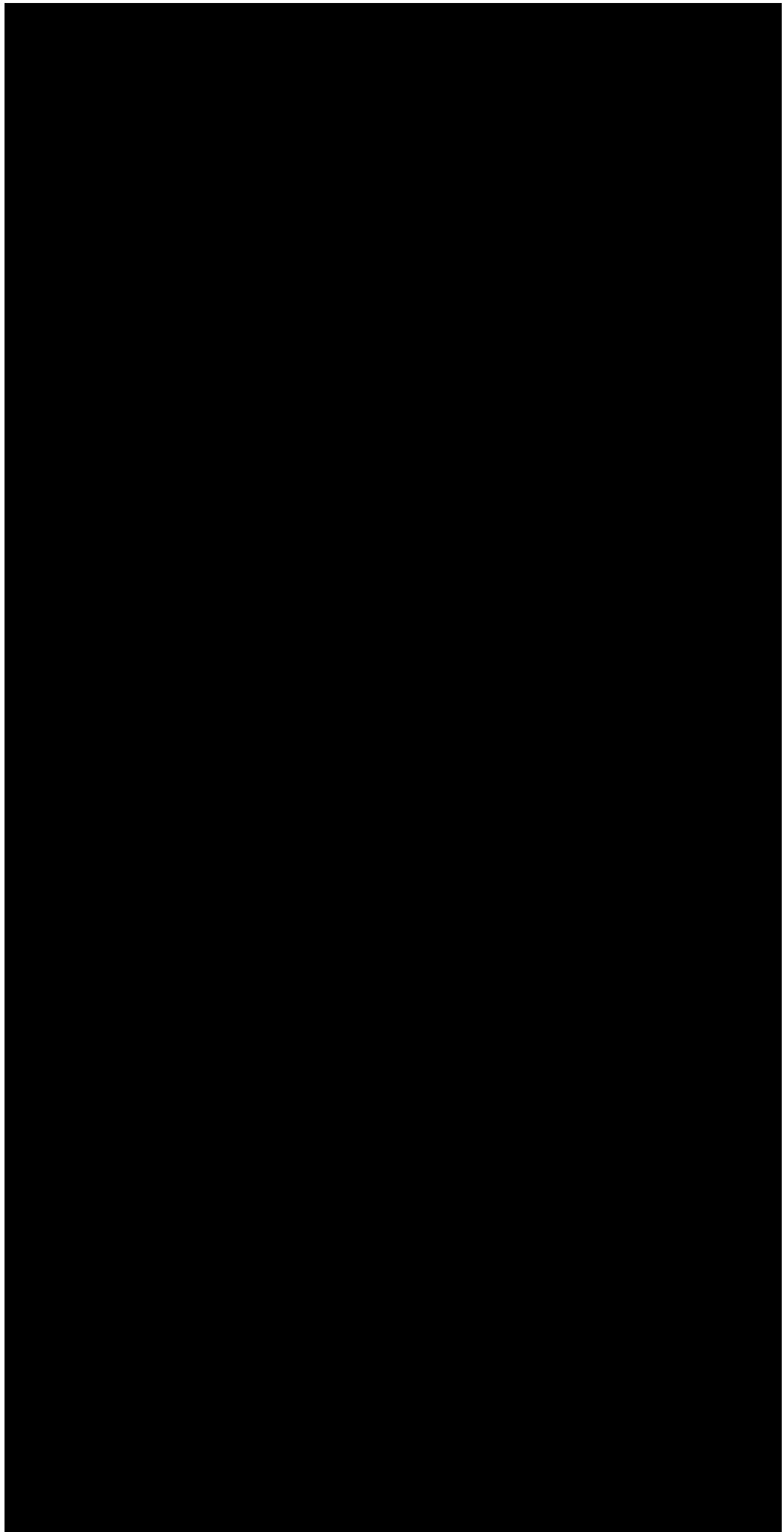
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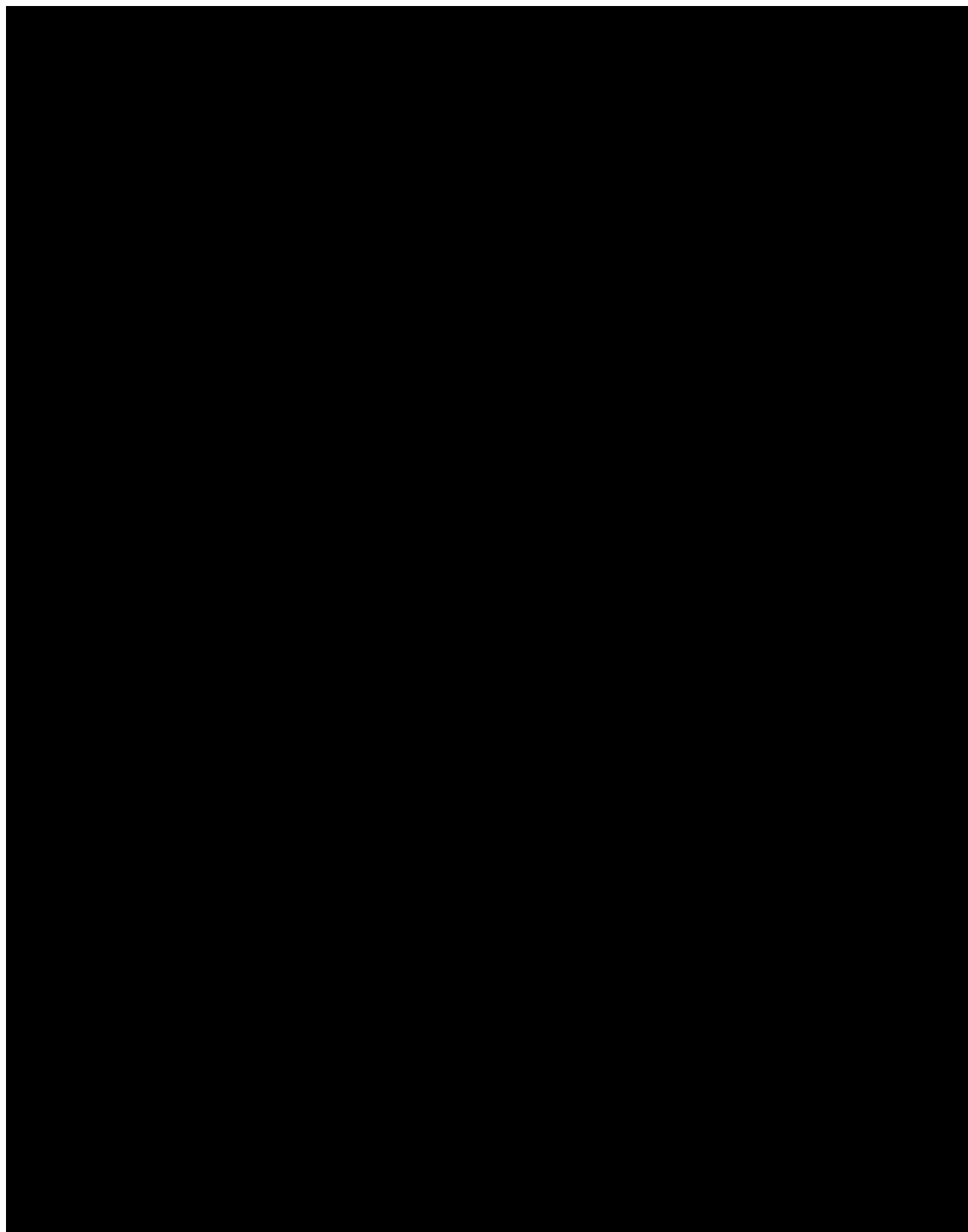
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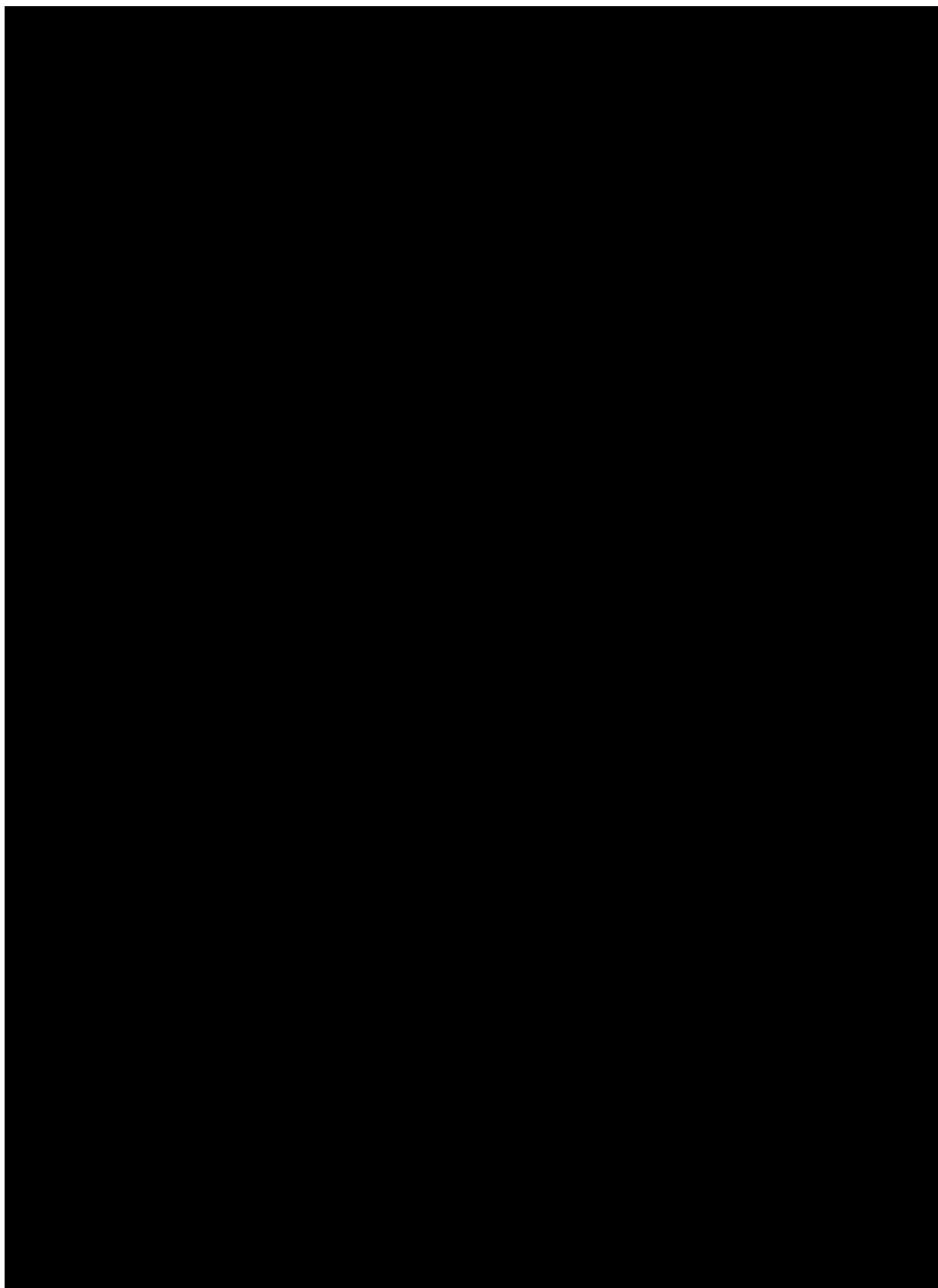
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## **SCHEDULE 2 – THE SERVICES**

### **A. Service Specifications**

#### **Appendix 2**

#### **Local Service Requirements**

# **NHS Type 2 Diabetes Path to Remission Programme (T2DR)**

## **ICS Prospectus**

## **Bedfordshire Luton and Milton Keynes Integrated Care System\***

**\* formerly the NHS Low Calorie Diet Programme – LCD, and may be referred to as such within this document.**

**All clarification questions should be raised formally through the clarification process on Atamis.**

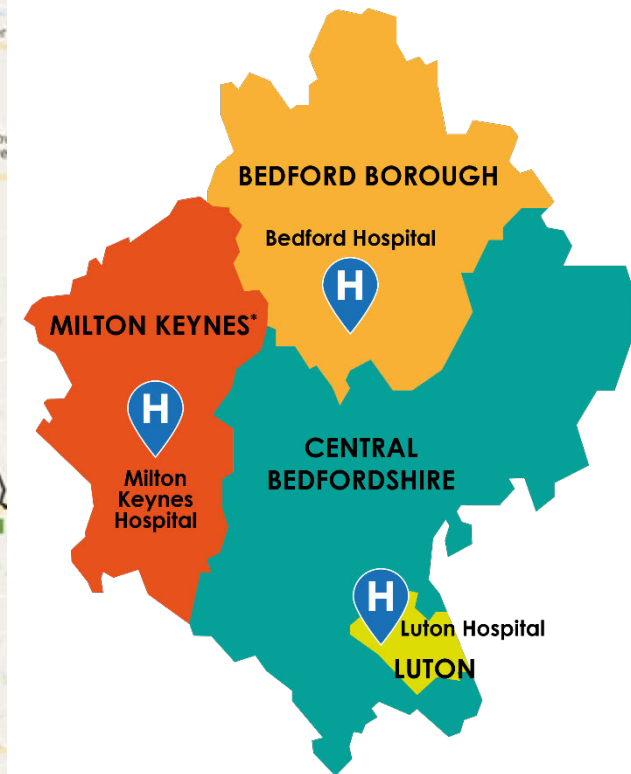
**Providers should not contact ICSs directly with queries in relation to the content of these prospectuses.**

<b>1.0 ICB/ ICS information</b>	
<b>1.1 ICB / ICS full name</b>	<b>Bedfordshire Luton and Milton Keynes ICS</b>
<b>1.2 Governance arrangements</b>	<p>The BLMK Low Calorie Diet Steering Group will provide strategic oversight across the ICS for implementation and successful delivery of the LCD programme. This will be chaired by the Clinical Lead and will have representation from each place, Public Health and the appointed Provider.</p> <p>The Steering Group will have delegated authority for decision making in relation to the programme and will be responsible for monitoring performance, facilitating collaboration between provider and local health economy, risk management, overall quality improvement and identifying and reducing inequalities in referrals and outcomes. It will take action to support improved performance and/or adjust activity flow as necessary and will work closely with the Provider to optimise pathways, patient experience and the interface with GP practices, while collaborating on reducing barriers to access and addressing any issues which arise.</p> <p>As members of the Steering Group, the place-level representatives will be responsible for working directly with their constituent PCNs to support appropriate identification of patients and high quality referrals with safe management of medications, in line with guidance and protocols. The Steering</p>



	<p>Group will also be responsible for liaising directly with the NHS Diabetes Programme and NHS Regional teams and completing necessary reporting.</p> <p>This group will report into the overarching BLMK Diabetes Group, which reports into the BLMK Primary Care Commissioning and Assurance Committee (a sub-committee of the ICB Board) via the Primary Care Delivery Group.</p>
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2.0 ICB / ICS Partnership Geography	
2.1 Geographical spread	



\*The area covered by the ICB also includes the following Lower Layer Super Output Areas in the County of Buckinghamshire:  
E01017695, E01017696, E01017669, E01017670

The total population covered by BLMK ICS is approximately one million, with 991,800 'usual residents' identified in the 2021 census. There were 185,300 people in Bedford Borough, 294,200 people in Central Bedfordshire, 225,300 people in Luton, and 287,000 people in Milton Keynes.

There are four 'places' aligned with the local authority areas – Luton, Central Bedfordshire, Bedford Borough and Milton Keynes. These are also aligned to the former CCG footprints, with Central Bedfordshire and Bedford Borough in combination sharing the footprint of the former Bedfordshire CCG (referred to here as Bedfordshire place).

Across the ICS, there are a total of 93 GP practices with located in Bedfordshire, in Luton and in Milton Keynes, split into a total of 23 Primary Care Networks (PCNs). These are:

<b>Bedford Borough</b>	<b>Central Beds</b>	<b>Luton</b>	<b>Milton Keynes</b>
Caritas East Bedford North Bedford Unity	Chiltern Hills Hilton Leighton Buzzard Sandhills Titan Ivel Valley South	Lea Vale eQuality Hatters Health Medics Phoenix Sunrisers Oasis	Ascent The Bridge Crown East MK Nexus South West Watling Street

<p><b>2.2 Urban/Rural</b></p>	<p>Bedford Borough contains one large urban area that comprises Bedford and the adjacent town of Kempston, surrounded by a large rural area with many villages. 64% of the borough's population live in the town of Bedford, with the other 36% living in the surrounding 45 parishes. Central Bedfordshire is a mainly rural location with a mix of small market towns and villages. Population densities of Bedford Borough and Central Bedfordshire are 389 and 411 people per square kilometre respectively.</p> <p>Luton is predominantly urban. In addition to the urban centre of Luton town, it includes more suburban areas bordering Hertfordshire and Bedfordshire. It has a population density of 5196 people per square kilometre.</p> <p>Milton Keynes covers both urban and rural areas with an overall population density of 930 people per square kilometre. While the majority of its population reside in the large town of Milton Keynes, it also includes the towns of Bletchley, Wolverton and Stony Stratford, along with another fifteen villages and intervening farmland.</p> <p>The areas making up BLMK ICS vary considerably in demographics and socioeconomic deprivation – Luton is particularly diverse with 55% of the population from ethnic minority backgrounds. Its population is also generally younger with greater levels of deprivation. This is in contrast to Central Bedfordshire, with a much lower proportion of its population from ethnic minority backgrounds, an older population and lower levels of deprivation.</p>
<p><b>2.3 Transport links and car usage</b></p>	<p>Across the ICS, transport links are well developed and 84% of households have a motor vehicle.</p>

Place / Local Authority	Households with car or van available	Households without car or van available	% of households with car/van availability
Bedford Borough	63812	13137	83%
Central Bedfordshire	104399	13820	88%
Luton	74293	20389	78%
Milton Keynes	98584	18659	84%

There is also generally good access to public transportation, however, in rural Bedfordshire, this is more limited in reach and frequency. The local authorities have collated details of local public transport provision within each of the four boroughs:

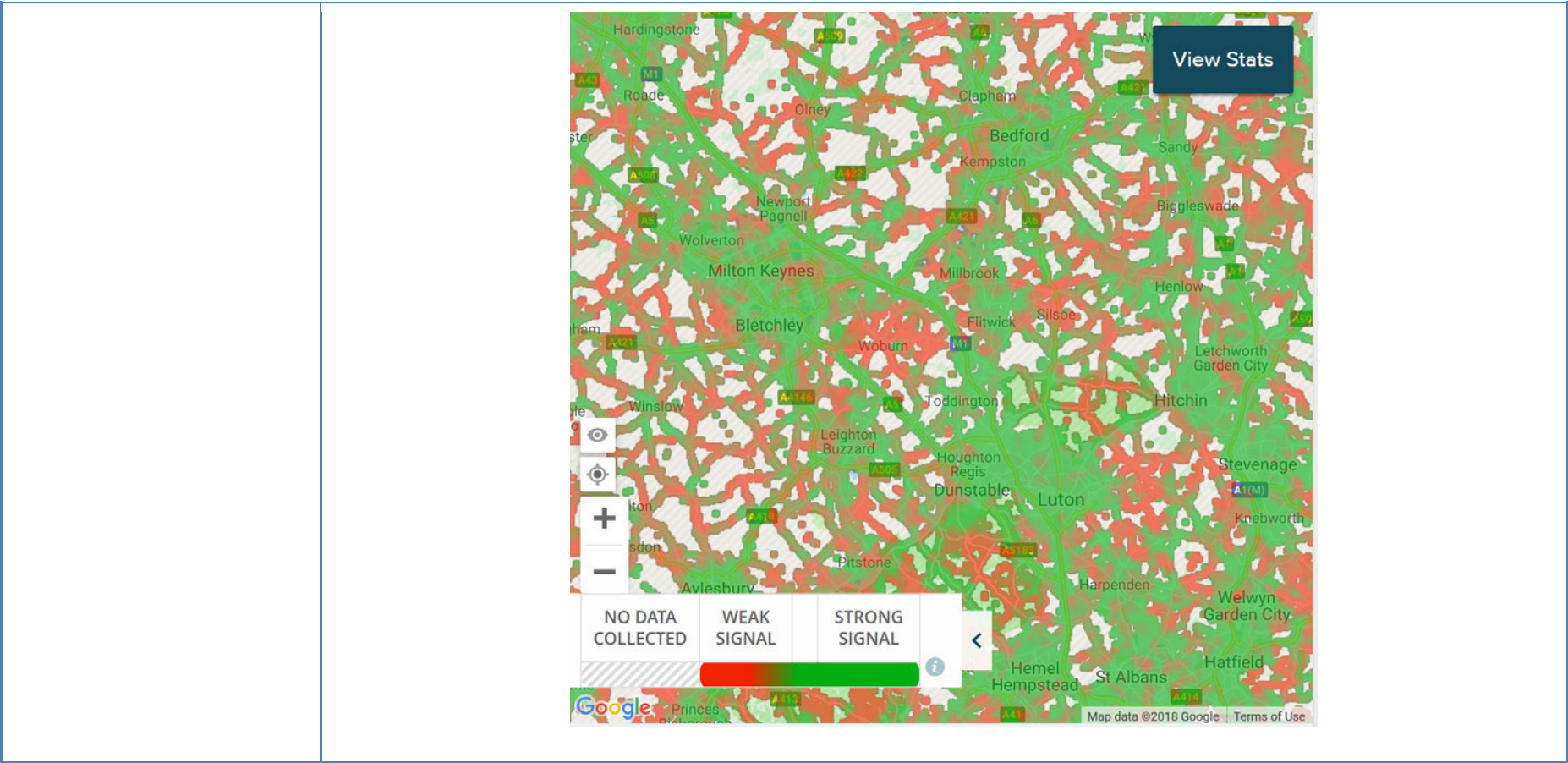
Bedford - [Public transport | Bedford Borough Council](#)

Central Bedfordshire - [Public transport - | Central Bedfordshire Council](#)

Luton - [Public transport \(luton.gov.uk\)](https://www.luton.gov.uk)

	Milton Keynes - <a href="#">Transport hub</a>   <a href="#">Milton Keynes City Council (milton-keynes.gov.uk)</a>
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<p><b>2.4</b> Any challenges with digital access – e.g. specific areas lacking broadband availability</p>	<p>Throughout BLMK, there is good access to broadband. Data is not available at Local Authority level regarding internet access, however we expect to be in line with national trends (9 out of 10 households have internet access and 9 out of 10 people own a smartphone). Local authority libraries have free internet access with many providing short courses on digital literacy.</p> <p>Mobile phone signal coverage is good in Luton, Milton Keynes and Bedford town although weaker in some rural parts of Bedfordshire:</p>
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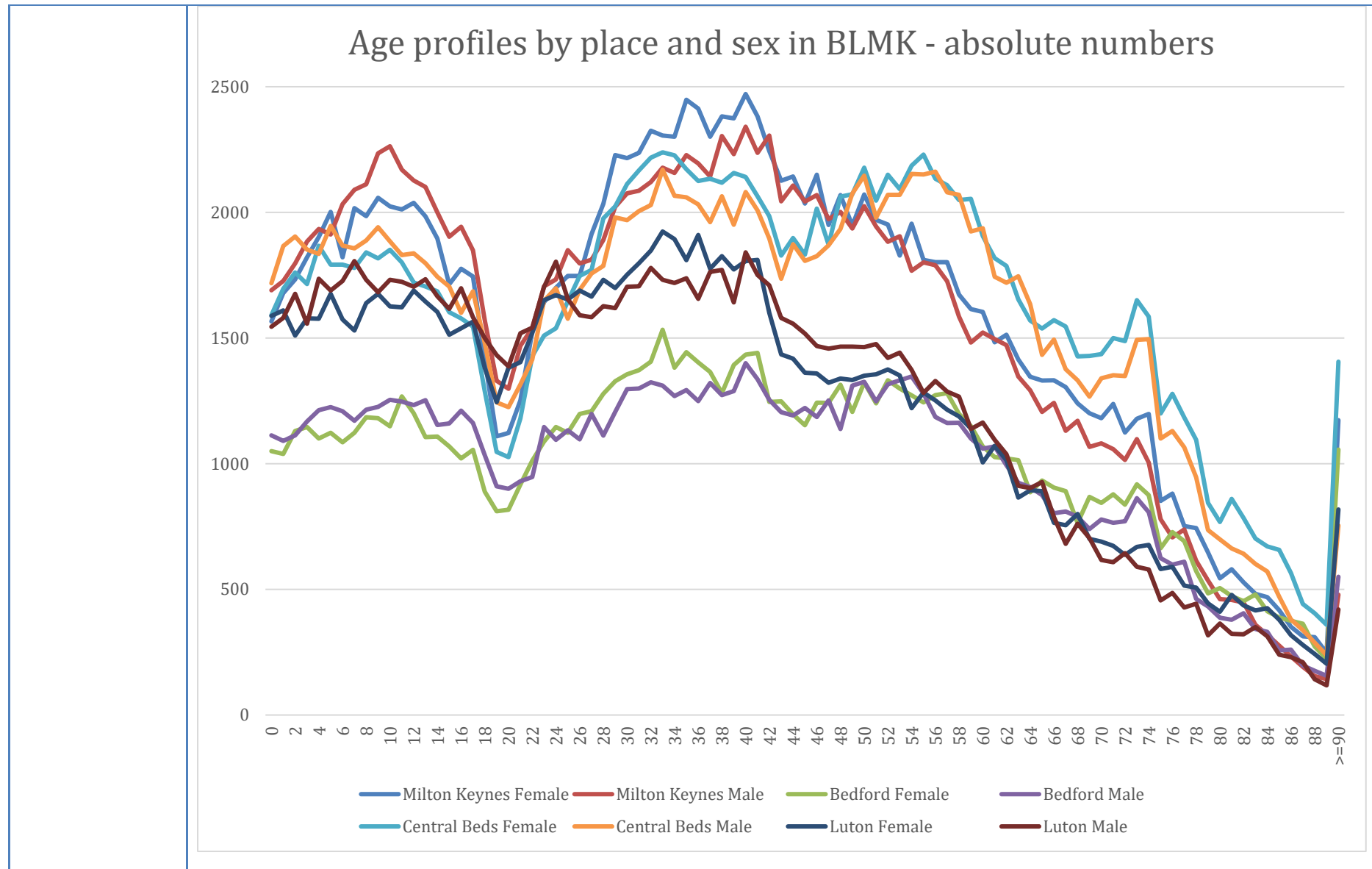
### 3.0 ICS Partnership Demographics

**3.1** State the total population numbers in each age group, by gender and Place Level

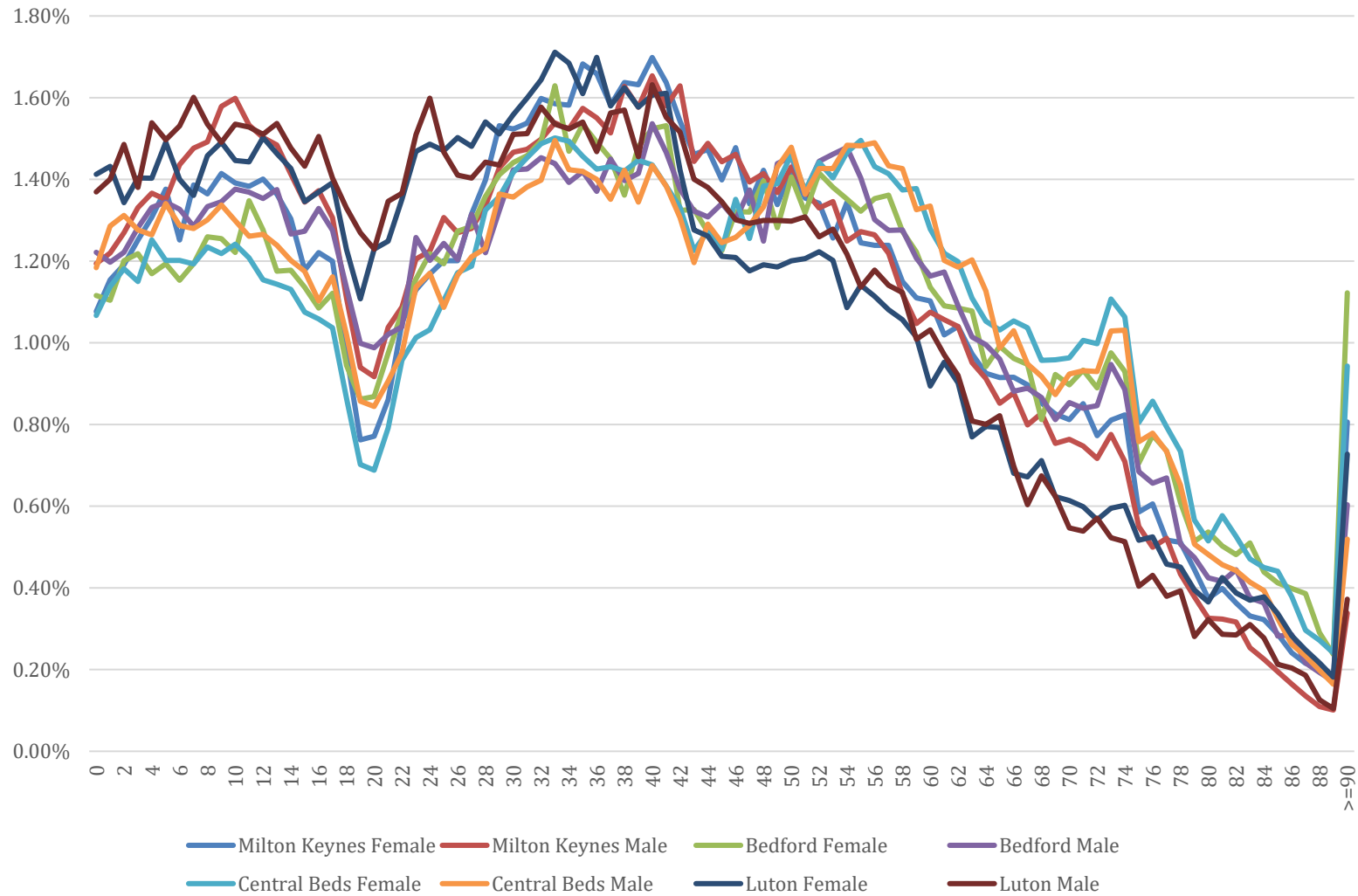
	Bedford Borough		Central Beds		Luton		Milton Keynes	
Age	Male	Female	Male	Female	Male	Female	Male	Female
<18	21,418	20,139	32,760	31,142	30,187	28,761	35,770	33,773
18-25	8,095	7,803	11,603	10,665	12,541	11,907	12,497	11,513
26-35	12,406	13,506	19,515	20,654	16,798	17,811	20,367	21,756
36-45	12,741	13,160	19,409	20,282	16,789	16,717	21,952	22,871
46-55	12,735	12,715	20,273	20,906	14,316	13,289	19,306	19,703
56-65	10,440	10,851	18,451	18,618	11,060	10,535	14,918	15,584
>65	13,292	15,923	23,121	26,853	11,133	13,411	16,763	20,288

In view of the eligibility criteria for the LCD programme, the categories for age in the table above have been chosen to provide optimal utility for potential providers. Ineligible age bands (<18 and >65) have been grouped together, while the eligible age band (18-65) has been sub-divided to support better understanding of the underlying composition. The same approach has been used for categorising the eligible population in Q3.6

For completeness, the full age profiles of each place, by sex, are shown below – as absolute numbers and then as proportion of total place population:



## Age profiles by place and sex in BLMK - as % of place population



**3.2** Set out the most prevalent non-English speaking languages across the ICB / ICS footprint, including a list of the top 5 non-English speaking languages

According to the 2021 census:

	% in Bedford Borough	% in Central Bedfordshire	% in Luton	% in Milton Keynes
<b>Can speak English well / very well</b>	77.8	87.1	75.9	86.3
<b>Cannot speak English well</b>	19.1	10.9	20.5	11.9
<b>Cannot speak English</b>	3.0	2.0	3.6	1.7

The top 5 non-English languages spoken in BLMK are:

	Number of people	% of population
<b>Polish</b>	20,061	2.1
<b>Romanian</b>	18,404	1.9
<b>Urdu</b>	11,260	1.2
<b>Bengali</b>	8,659	0.9
<b>Punjabi</b>	6,011	0.6

However, there is considerable variation by place for each of these languages, as shown below:

	% in Bedford Borough	% in Central Bedfordshire	% in Luton	% in Milton Keynes	% in BLMK
<b>Polish</b>	2.7	1.0	3.6	1.6	2.1
<b>Romanian</b>	1.6	1.0	3.5	1.9	1.9
<b>Urdu</b>	0.5	0.1	4.0	0.5	1.2
<b>Bengali</b>	0.7	0.0	2.9	0.3	0.9
<b>Punjabi</b>	1.3	0.1	1.2	0.3	0.6

**3.3** Set out the main ethnicities, cultural needs and/or other population groups present within the ICB / ICS partnership that may require the intervention to be tailored

The table below shows the breakdown of ethnicities of the population by each of the four 'place' areas

	Bedford Borough		Central Bedfordshire		Luton		Milton Keynes		BLMK	
	Number	%	Number	%	Number	%	Number	%	Number	%
Total population	185,224	100	294,251	100	225,261	100	287,060	100	991,796	100
Asian or Asian British: Bangladeshi	4,486	2.4	572	0.2	20,630	9.2	3,189	1.1	28,877	2.9
Asian or Asian British: Chinese	756	0.4	1,368	0.5	901	0.4	2,913	1.0	5,938	0.6
Asian or Asian British: Indian	10,074	5.4	4,684	1.6	12,096	5.4	15,348	5.3	42,202	4.3
Asian or Asian British: Pakistani	5,297	2.9	1,312	0.4	41,143	18.3	7,163	2.5	54,915	5.5
Asian or Asian British: Other Asian	2,650	1.4	2,385	0.8	8,555	3.8	7,032	2.4	20,622	2.1
Black, Black British, Caribbean or African: African	5,448	2.9	3,942	1.3	11,774	5.2	21,502	7.5	42,666	4.3
Black, Black British, Caribbean or African: Caribbean	3,227	1.7	2,148	0.7	8,216	3.6	2,975	1.0	16,566	1.7

	Black, Black British, Caribbean or African: Other Black	1,173	0.6	928	0.3	2,745	1.2	3,374	1.2	8,220	0.8
	Mixed or Multiple ethnic groups: White and Asian	2,146	1.2	2,572	0.9	2,429	1.1	2,973	1.0	10,120	1.0
	Mixed or Multiple ethnic groups: White and Black African	939	0.5	1,095	0.4	1,268	0.6	2,551	0.9	5,853	0.6
	Mixed or Multiple ethnic groups: White and Black Caribbean	3,638	2.0	3,121	1.1	3,486	1.5	2,997	1.0	13,242	1.3
	Mixed or Multiple ethnic groups: Other Mixed or Multiple ethnic groups	1,863	1.0	2,097	0.7	2,437	1.1	3,204	1.1	9,601	1.0
	White: English, Welsh, Scottish, Northern Irish or British	118,779	64.1	245,769	83.5	71,532	31.8	71,532	62.2	178,568	62.0
	White: Irish	1,798	1.0	3,527	1.2	4,570	2.0	2,382	0.8	12,277	1.2
	White: Gypsy or Irish Traveller	208	0.1	436	0.1	238	0.1	156	0.1	1,038	0.1
	White: Roma	483	0.3	297	0.1	808	0.4	578	0.2	2,166	0.2



White: Other White	18,906	10.2	15,516	5.3	24,650	10.9	24,430	8.5	83,502	8.4
Other ethnic group: Arab	557	0.3	493	0.2	2,106	0.9	1,349	0.5	4,505	0.5
Other ethnic group: Any other ethnic group	2,796	1.5	1,989	0.7	5,677	2.5	4,376	1.5	14,838	1.5

The five largest ethnic minority groups in BLMK are Other White, Pakistani, Black African, Indian and Bangladeshi, although the proportions of the place-level population represented by each category varies markedly. These ethnic minority groups may have their own cultural and culinary needs and may benefit from being offered tailoring of the programme. We would be keen for appropriately adapted content, taking into account language and cultural context, to be available for these populations with culturally relevant advice offered regarding diet and physical activity.

Luton is highly diverse with most of its population not identifying as White British. There is a much higher proportion of Pakistani and Bangladeshi ethnicity in Luton, while Black African ethnicity has a greater proportion in Milton Keynes. The largest ethnic minorities in Bedford Borough are Other White (which would include Polish and Romanian) and Indian, which represent similar proportions of the population as seen in Luton and Milton Keynes for these ethnicities. Central Bedfordshire has much less ethnic diversity overall, with the largest ethnic minority being Other White.

Noting that over 30% of Luton's population identify as being from South Asian ethnicities, we would ask the provider to specifically target engagement with these ethnicities. Some areas within Luton are predominantly composed of residents of South Asian origin; working with these local communities to ensure services are

	<p>appropriately tailored and meet their cultural and culinary needs is key to success of the programme locally. South Asian ethnicities are likely to show greater proportional representation in the population eligible for the programme, given their much greater risk of developing type 2 diabetes at lower BMI and younger ages than white ethnicities. However, it should be noted that there are key cultural differences and varying requirements for adaptation, including language, between Pakistani, Bangladeshi and Indian ethnic populations.</p> <p>Our Public Health team are keen to support the Provider with relevant insights on the local population and link them to lifestyle services which have already incorporated adaptations to meet varying cultural needs. We also have well developed fora for supporting engagement with our population and specific communities, e.g. the Luton Council of Faiths, MK Equality Council and Bedford Faith Leaders Group.</p>
<p><b>3.4</b> Describe any population segments in your area with poorer health outcomes (i.e. those subject to the greatest inequalities) and outline how you would work with the</p>	<p>All areas in BLMK have already had access to the NHS LCD Programme and the vast majority of practices have sent referrals. However, when segmenting by ethnicity, there are inequalities present at each step of the pathway. Uptake rates (from referral to starting TDR) are lower in people of Asian ethnicity than White ethnicity in BLMK (59% vs 80%) and, after starting TDR, retention is poorer for people of Asian ethnicity compared to White ethnicity. 12 month weight change data is also suggestive of inequalities in outcomes in people of Asian ethnicity. Compared to the eligible population, referral rates are lower in people from the most socioeconomically deprived quintile than other quintiles and uptake rates are lower, although there are no other clear signals in our local data for the programme for inequalities by deprivation thus far (noting that such signals are seen in the much larger national datasets).</p> <p>More broadly in relation to type 2 diabetes, NDA data for care process delivery does not reveal marked inequality by ethnicity in BLMK (if anything, people with White ethnicity are slightly less likely to have all 8 care processes than people of Asian ethnicity overall). Inequalities for care process delivery and treatment target</p>

<p>provider to improve outcomes in these groups.</p>	<p>achievement are seen in relation to socioeconomic deprivation, with a linear relationship seen between these and IMD quintile.</p> <p>Therefore, the population segments for whom we would seek to prioritise activities to reduce inequalities and improve outcomes, particularly in relation to the NHS LCD programme, are people of Asian ethnicity and people living in the most socioeconomically deprived areas in BLMK.</p> <p>We would work with the Provider to gather insights into the drivers for the differential outcomes by ethnicity thus far and explore the particular barriers and challenges which resulted in lower uptake, retention and weight loss on the programme until now. Drawing on their experience of delivery and combined with our understanding of the data and links to practices, participants and key engagement fora, we would support the Provider in ensuring appropriate adaptations and tailoring to meet the needs of our population from Asian ethnicities. We would also explore how referrers may be supported to have better quality referral conversations and provide appropriately adapted material at the outset to drive higher rates of uptake from referral.</p> <p>Further, we will focus engagement activities with the provider on practices in the most deprived areas in BLMK as well as those serving populations with a high proportion of Asian ethnicity. This will aim to increase referral rates of the currently under-represented segments (in relation to those eligible for the programme) of our population in BLMK.</p> <p>Given that our previous experience with the programme has been digital-only, we anticipate that the inclusion of the option for face-to-face delivery may also help in reducing inequalities, through providing a route of delivery for those who are less digitally-enabled. We would work with the Provider to ensure that timings and venues are</p>
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	suitable for our population and particularly aimed at reduction of inequalities, with particular considering of modes of travel and cost for people living in the most deprived areas.					
<b>3.5</b> Type 2 diabetes prevalence						
		<b>Bedford Borough</b>	<b>Central Beds</b>	<b>Luton</b>	<b>Milton Keynes</b>	<b>BLMK</b>
	<b>Type 2 Diabetes Prevalence (as % of adults only)</b>	8.10%	7.10%	10.30%	8.00%	8.30%
	<b>Type 2 Diabetes Prevalence (as % of total pop)</b>	6.30%	5.60%	7.60%	6.10%	6.30%
<b>3.6</b> Numbers identified as potentially eligible for the NHS LCD programme	We have used system searches incorporating all objective eligibility criteria to model the numbers of people potentially eligible for the programme. The only criteria which have not been included are those which cannot be reliably established through coding and require an individualised assessment (e.g. whether someone is able to understand and meet the demands and monitoring requirements of the programme).					

Using this approach, the following table details the numbers at place-level and at overall BLMK level (note that Central Bedfordshire and Bedford Borough have been combined as Bedfordshire due their sharing of a SystemOne Reporting Unit). Note that the first row does not exclude people with HbA1c and/or BMI results more than 12 months old, meaning these figures will include some people who could not be referred until repeat readings had been obtained (but who are likely to be eligible once these are available). The second row does exclude anyone with HbA1c and/or BMI results more than 12 months old, therefore entirely representing people who could be referred to the programme right now without requirement for repeat readings.

	<b>Bedfordshire</b>	<b>Luton</b>	<b>Milton Keynes</b>	<b>BLMK</b>
<b>Eligible on last results (no timeframe)</b>	3802	3425	2494	9721
<b>Eligible on last results (within 12m)</b>	2792	2663	1845	7300

	Bedfordshire		Luton		Milton Keynes		BLMK	
Age	Male	Female	Male	Female	Male	Female	Male	Female
18-25	6	15	6	13	4	6	16	34
26-35	77	92	90	123	55	63	222	278
36-45	313	300	403	377	256	234	972	911
46-55	745	548	705	566	510	382	1960	1496
56-65	919	787	618	524	555	429	2092	1740

In Line with the approach used for Q3.1 and to assist the Provider with modelling of potential delivery routes, the above figures have been broken down by age and sex. The following table shows this breakdown for those eligible based on last results, without excluding those with HbA1c / BMI readings more than 12 months old:

	Bedfordshire		Luton		Milton Keynes		BLMK	
Age	Male	Female	Male	Female	Male	Female	Male	Female
18-25	4	8	4	11	2	4	10	23
26-35	54	67	71	93	37	44	162	204

	<b>36-45</b>	220	219	304	297	179	175	703	691
	<b>46-55</b>	511	422	551	444	360	303	1422	1169
	<b>56-65</b>	680	607	473	415	422	319	1575	1341
	<p>The following table shows a similar breakdown by age and sex for those eligible based on last results and with all results within the last 12 months – i.e. who are eligible to be referred right now without further readings:</p>								
<b>3.7</b> Existing local provision of locally commissioned Total Diet Replacement (TDR), other Low Calorie Diet (LCD) / type 2 diabetes remission programmes	There are no such locally commissioned programmes.								

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#### 4.0. Intervention allocation and monthly profiling

**4.1** Intervention allocation to the ICB / ICS for the 2 year contract.

Year	Year 1	Year 2	Total
<b>Allocation</b>	250	250	<b>500</b>

*Allocation means the number of places used on the NHS LCD (people who commenced TDR / programme starts).*





<p>If you need to increase referral activity, how would this be accomplished?</p>	<p>We will closely monitor the data on referrals and TDR starts with the provider. If high activity levels indicate that the allocated number of places are likely to be exhausted prematurely, we will discuss next steps with the commissioner. If needing to reduce such activity, our first step is likely to relate to adjusting the financial incentive available.</p> <p>If needing to increase activity, in line with delivery considerations and capacity of the provider</p> <p>, there are a number of initiatives that we have ready to implement. These include activating a pop-up which would appear when the records of eligible patients were accessed (more obviously flagging eligibility than our current alert / icon). This may be further directed to reduce inequalities through only being activated at certain practices (e.g. those in the most deprived areas of BLMK) or through the records of people from specific under-represented population groups (e.g. people with ethnicity which is underrepresented in referral / uptake compared to the eligible population).</p> <p>Targeted engagement work with lower-referring practices and underrepresented population groups would also support increases in activity. Further ‘boosts’ in referral activity could be accomplished through supporting such practices, and/or those in the most deprived areas, to run searches for eligible patients followed by the offer of referral if clinically appropriate. Similarly to pop-ups, these could be easily configured to specifically address inequalities.</p>
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## 5.0. Planned mobilisation and transitio

**5.1** Outline the details of how the ICB / ICS will work with existing and/ or new NHS LCD providers to ensure successful mobilisation/ seamless transition of services.

Following confirmation of incoming provider, if there is a change from the incumbent, we would seek to arrange and facilitate early discussion between the existing and new providers on transition of services. We aim to work very closely with both providers to ensure as seamless as possible a transition for referrers and any people who have been referred but not commenced the service. Key delivery milestones and timelines would be developed in collaboration with the providers.

We recognise that it is essential to work closely with the incoming provider to ensure the NHS LCD Programme can continue to be delivered to our population for optimal benefit with minimal delay. We would work with the provider to refine all aspects of the pathway and use our local knowledge and contacts to facilitate the mobilisation process as much as possible. The Clinical Lead in BLMK is strongly positioned to work with the Provider in implementing the programme locally, having been closely involved with development of the specification as the Primary Care Advisor to the Diabetes Programme at NHS England.

The Clinical Lead and Implementation Leads will work closely with the provider throughout mobilisation, advising on local context, co-designing mobilisation approach, communications and supporting resources (including referral forms), and helping overcome any identified issues. We will also work with General Practices to ensure referral flow is appropriately managed during transition to the new contract, taking a flexible approach aiming to match referral flow to their requirements when mobilising. In addition, we will work with the Provider to ensure a continued safe, responsive interface with GP practices. This is particularly important in case of any adverse or concurrent events, with clear and well-defined roles and responsibilities, pathways and routes for escalation and communication.

	<p>We will also support the provider with lists of potential venues and contact details as well as facilitating introductions where additional possible venues are identified. Further, we will ensure the incoming provider has access to a comprehensive directory of local services and link them with key stakeholders.</p> <p>We are keen to minimise any waiting list to be transferred to the new provider. We will therefore closely monitor any waiting list over the months prior to contract end and will work together with the existing provider to keep the list to a minimum.</p> <p>We will develop a joint working forum with incumbent and incoming providers. This will involve:</p> <ul style="list-style-type: none"> <li>• Mutually agreeing transition arrangements</li> <li>• Taking action to minimise transfer of waiting list</li> <li>• Working with clinical leads and the incoming and incumbent providers to identify any required pathway changes and implementing any necessary actions to facilitate these</li> <li>• Agreeing dates for switch over of referral forms and email address for receiving referrals</li> <li>• Clear communication with primary care before, during and after the transition phase so they are fully informed of the process and any changes in service offer and referral pathway</li> <li>• Working together to enhance communication to other stakeholders</li> <li>• Engaging primary care to ensure service users referred into the programme during the transition period are informed of the service offer and what to expect</li> <li>• Collaborative working with existing / incoming service providers on the practical issues of transition – minimising disruption and easing the process through working together to plan ahead and to overcome or mitigate any identified issues</li> <li>• Agreement between the system partners and the incoming and incumbent provider regarding</li> </ul>
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	<p>the arrangements for transfer of information, in compliance with relevant legislation, consent and confidentiality</p> <p>The BLMK LCD steering group will ensure clear communications with General Practices regarding transition. This will include a refresh of guidance to referring GP practices, patient literature, health professional advice, referral pathways, referral forms and relevant templates within GP clinical systems. We would develop a transition plan in partnership with our incoming and incumbent providers which would cover:</p> <ul style="list-style-type: none"> <li>• Communication strategy</li> <li>• Transfer of referrals</li> <li>• Referral Forms</li> <li>• Data transfer</li> <li>• Incoming provider mobilisation</li> <li>• HR</li> <li>• Learning and Development</li> <li>• Supply chain and marketing</li> <li>• Stakeholder engagement</li> </ul>
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<b>6.0 Delivery plans</b>	
<b>6.1</b> Communications, engagement and training	There are a number of well established and effective communication channels with General Practice in BLMK. These include written communications through the weekly GP bulletin and correspondence directly to practices, as well as regular learning events such as monthly Protected Learning Time sessions and focussed webinars.

<b>6.0 Delivery plans</b>	
	<p>A number of other fora for communication exist for communicating with practices, such as the PCN meetings and Practice Manager forum, and for specific healthcare professional groups, such as the monthly nurse forum and clinical pharmacist forum. BLMK ICB also employs a number of place-based leads who work very closely with practices and are a key means of engagement and communication.</p> <p>Awareness of the NHS LCD Programme is already favourable in BLMK, with the vast majority of practices having referred to the programme. All of the aforementioned channels have been used during the course of the current contract to communicate with practices and referrers regarding the programme and will continue to be used to communicate changes and support awareness.</p> <p>Additionally, the BLMK Clinical Lead closely monitors data on referrals by practice and proactively contacts practices where referral flow is suboptimal to explore challenges and offer support. This has contributed to BLMK having the highest proportion of referring practices of any NHS LCD Programme pilot site (and the highest proportion of practices referring to the NHS DPP in England). This approach of monitoring data and contacting practices to drive engagement will continue under the new contract.</p>
<b>6.2</b> Primary care data systems used across the ICB / ICS	<p>All practices in BLMK use SystmOne. The community diabetes services also use SystmOne and records are integrated providing that relevant patient consent has been obtained. The specialist teams in the hospital trusts use a different IT system which, at present, does not integrate with SystmOne. However, work on ongoing on a BLMK Shared Care Record.</p>

**6.0 Delivery plans**

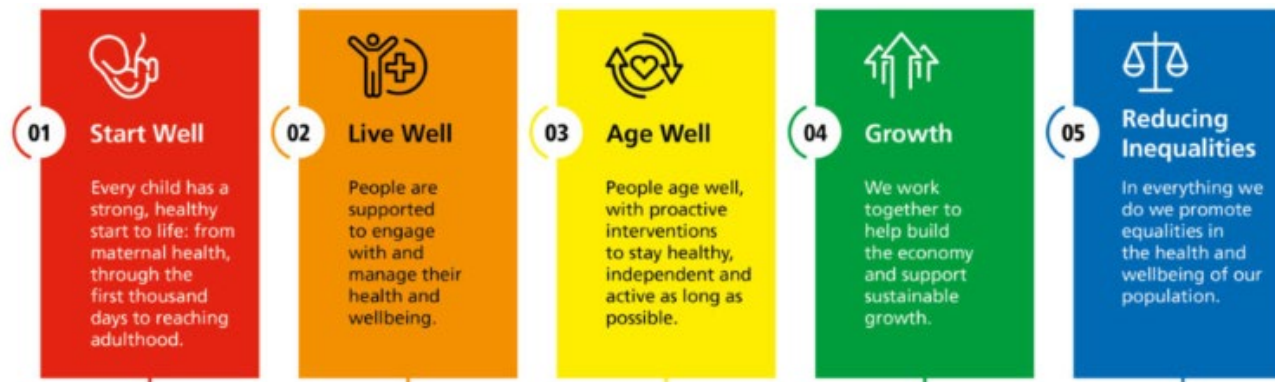
There is the facility at ICB level to centrally implement / update auto-populating referral forms and import resources into practice systems, enable alerts / pop-ups, and provide access to centrally-created searches. These approaches are already used extensively, with the BLMK Clinical Lead having created and rolled out various resources to all practices including the widely-shared search tools and alert / icon to reduce ineligible referrals and boost referral flow.

Additionally, there is functionality to run reports centrally. This has been used in the production of this prospectus to provide detailed breakdown of numbers of people eligible for the NHS LCD Programme by place, age and sex. This data is also routinely used by the ICB team to monitor referral flow against eligible population and thus identify high performing practices from whom to explore learning as well as lower performing practices to whom support may be offered. Additional uses are to support data gathering on decline rates, 6-month and 12-month reviews, and insights regarding remission rates.

## 7.0 Additional Information

**7.1** Other specific factors which a provider would need to consider in order to develop a service in this area (if not covered elsewhere in the prospectus)

- High levels of clinical engagement from primary care
- Strong clinical leadership
- Experienced ICB leads
- BLMK Clinical Lead was involved in writing the LCD service specification
- Track record of high rates of referral and innovative quality-improvement
- History of close working with providers to improve processes and the patient journey
- Exemplar nationally with approach to reducing ineligible referrals
- The NHS LCD Programme is aligned to multiple BLMK ICS strategic priorities



BLMK ICS is extremely well placed to support highly successful delivery of the NHS Low Calorie Diet Programme. The BLMK Clinical Lead has been written much of the national guidance, protocols and



**7.0 Additional Information**

materials for the programme. BLMK has previously been recognised in national publications for its extremely high clinical engagement with initiatives such as the NHS Diabetes Prevention Programme.

Given the previous experience with TDR-based programmes in BLMK (initially with an LCD pilot in Luton and then as a pilot site for the NHS LCD programme), we have high levels of clinical awareness regarding the attainment of remission of Type 2 diabetes through TDR and the eligibility criteria, necessary medication changes and clinical oversight required.

We are highly confident in our ability to generate activity in line with profile, flex this according to need and to increase this further should the opportunity arise. Although an indicative referral profile has been provided in this prospectus, we would be keen to support our Provider by adapting this as necessary according to their capacity and operational requirements as well as adjusting the modelling based on local data and insights.

## **SCHEDULE 2 – THE SERVICES**

### **A. Service Specifications**

#### **Appendix 3**

#### **Provider IPR**

Wellbeing Way app

## **SCHEDULE 2 – THE SERVICES**

### **Ai. Service Specifications – Enhanced Health in Care Homes**

Not Applicable

## SCHEDULE 2 – THE SERVICES

### Aii. Service Specifications – Primary and Community Mental Health Services

Not Applicable

**SCHEDULE 2 – THE SERVICES**

**B. Indicative Activity Plan**

<b>Not Applicable</b>
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## SCHEDULE 2 – THE SERVICES

### C. Activity Planning Assumptions

Not Applicable

# SCHEDULE 2 – THE SERVICES

## D. Essential Services (NHS Trusts only)

Not Applicable
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**SCHEDULE 2 – THE SERVICES**

**E. Essential Services Continuity Plan (NHS Trusts only)**

<p>Not Applicable</p>
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**SCHEDULE 2 – THE SERVICES**

**F. Clinical Networks**

<b>Not Applicable</b>
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# SCHEDULE 2 – THE SERVICES

## G. Other Local Agreements, Policies and Procedures

Not applicable
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## SCHEDULE 2 – THE SERVICES

### H. Transition Arrangements

Transition Arrangements are set out in the Transition section of the Service Specification at section 3.11

## SCHEDULE 2 – THE SERVICES

### I. Exit Arrangements

Exit arrangements are set out in the Transition section of the Service Specification at section 3.11

## SCHEDULE 2 – THE SERVICES

### J. Transfer of and Discharge from Care Protocols

Not Applicable

## SCHEDULE 2 – THE SERVICES

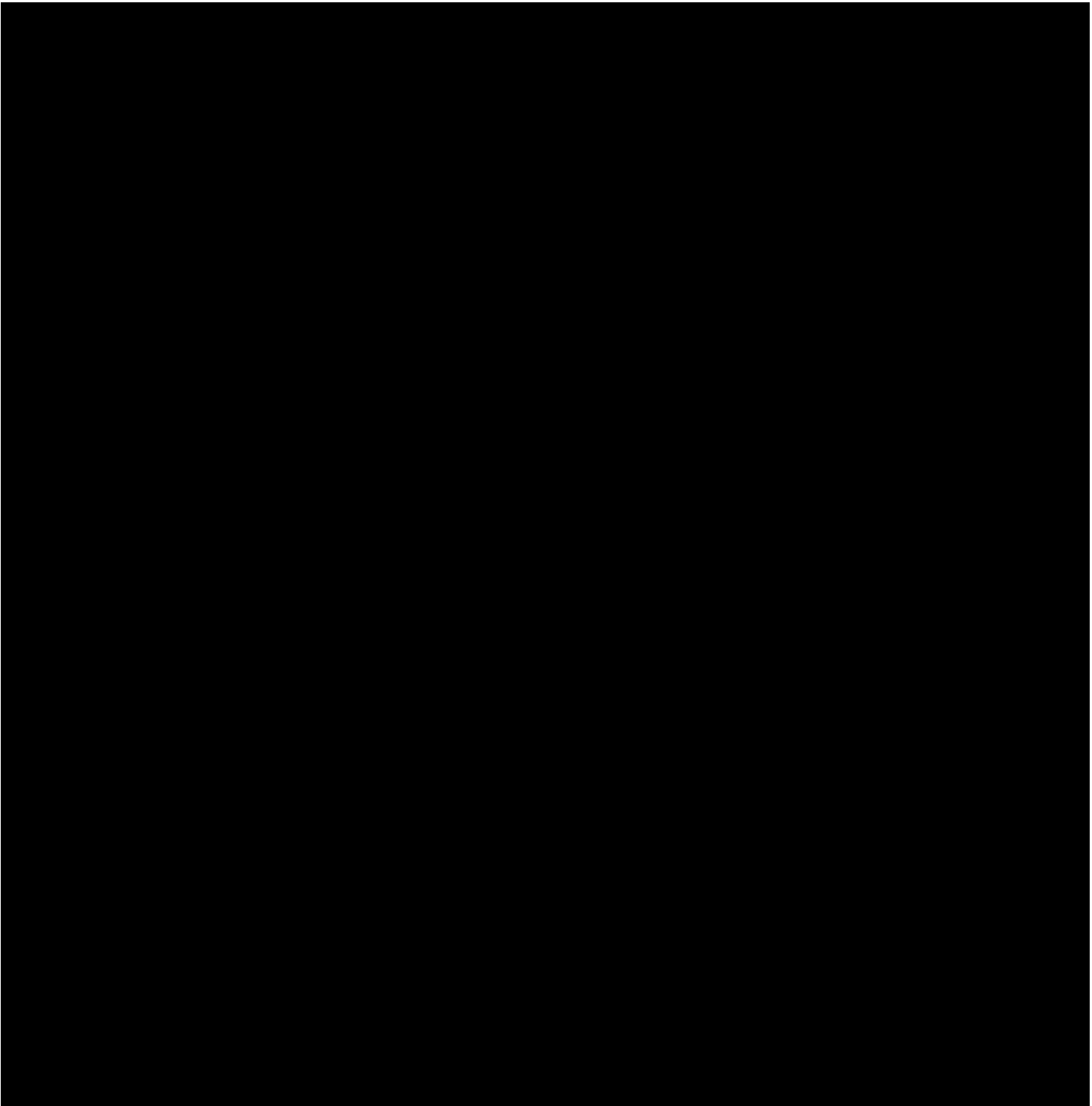
## K. Safeguarding Policies and Mental Capacity Act Policies

- Mental Capacity Act Policy
- Safeguarding Policy



Document History			
Version	Date	Changes made/comments	By whom
V1	Nov 2021	New Document	AM







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2. A horizontal bar chart with 10 bars of varying lengths. The bars are arranged in a zig-zag pattern, alternating between the left and right sides of the chart area. The lengths of the bars vary significantly, with some being very long and others being very short. The bars are colored in a light blue/teal shade.

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Government	Percentage
Current government	85%
Previous government	15%












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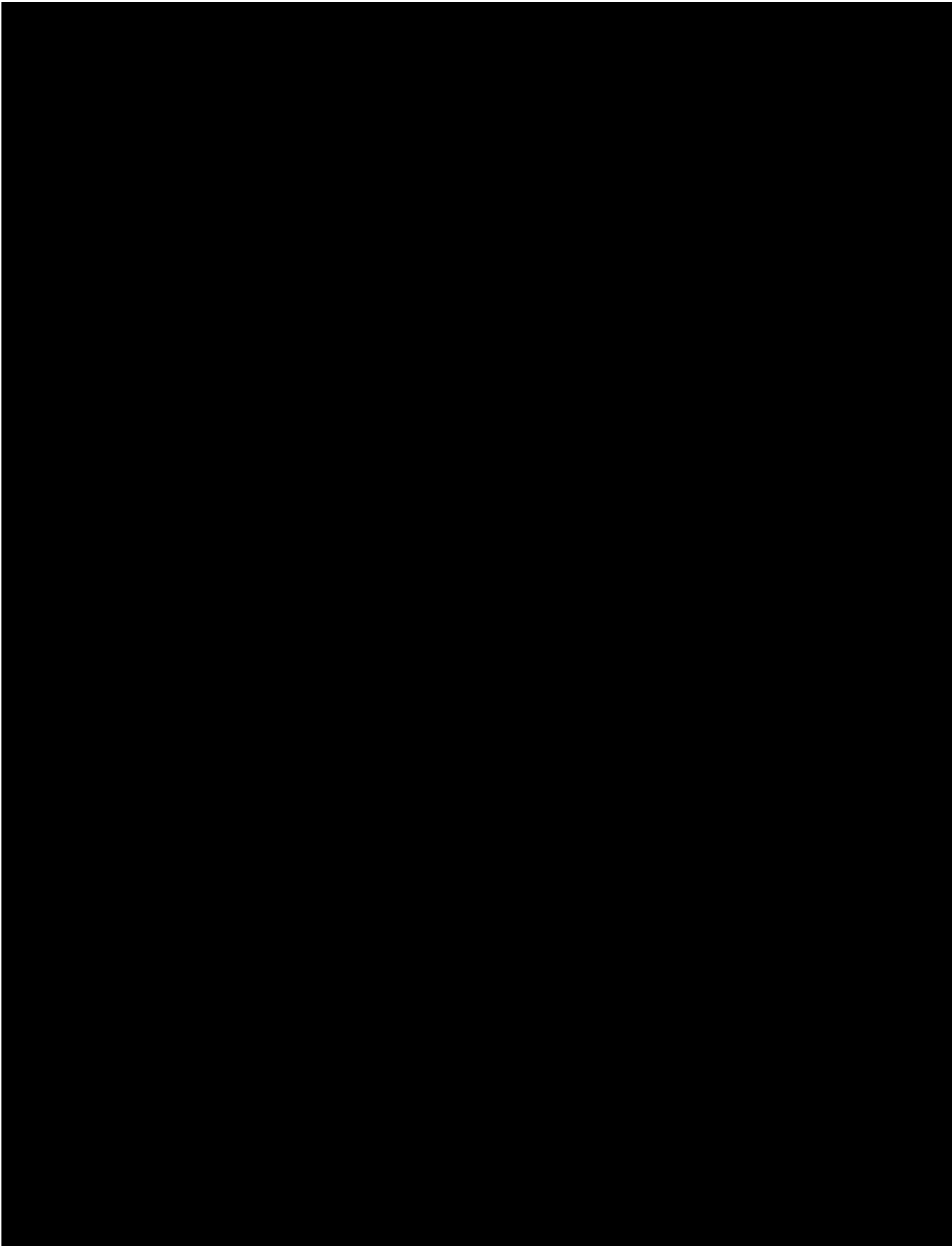
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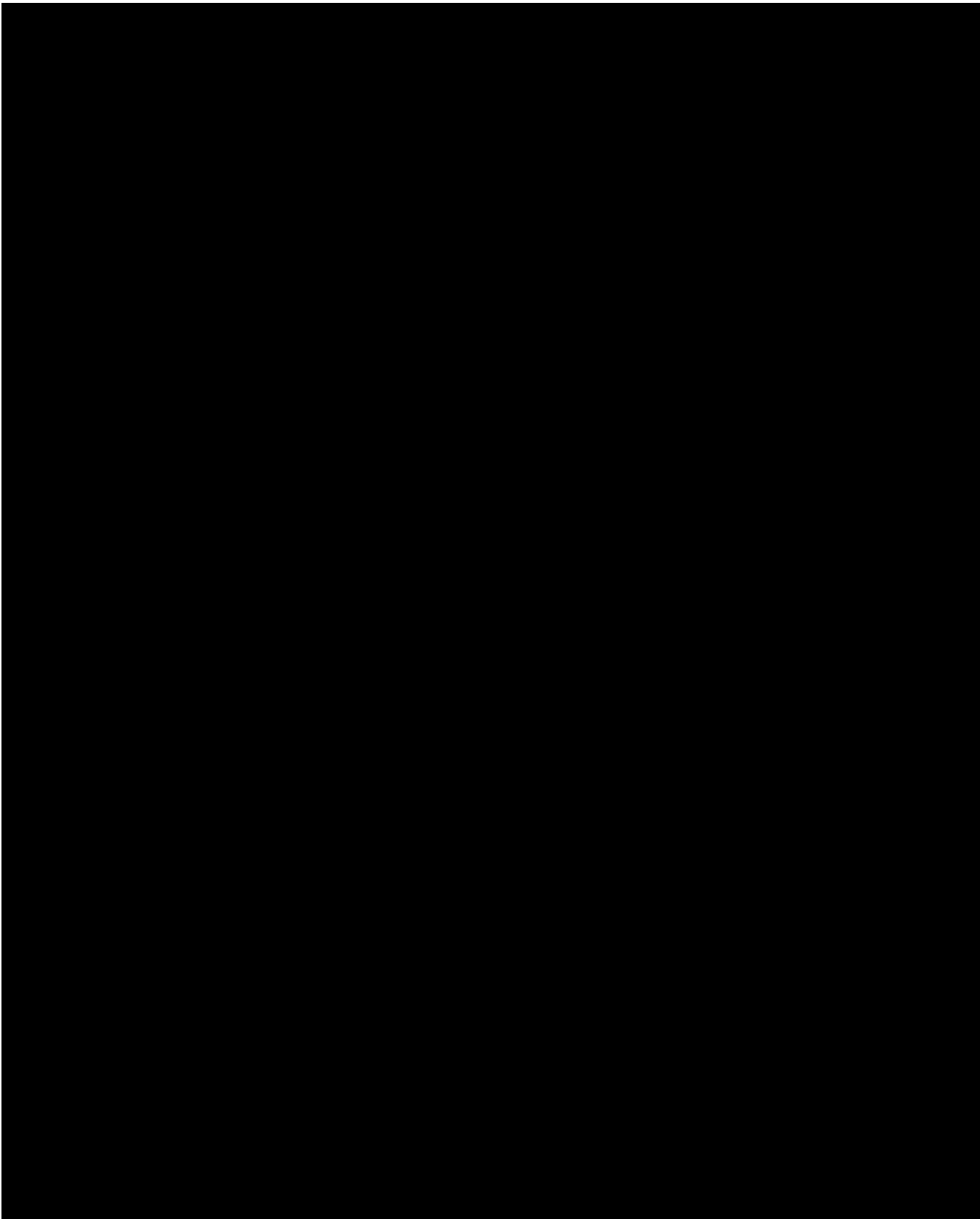


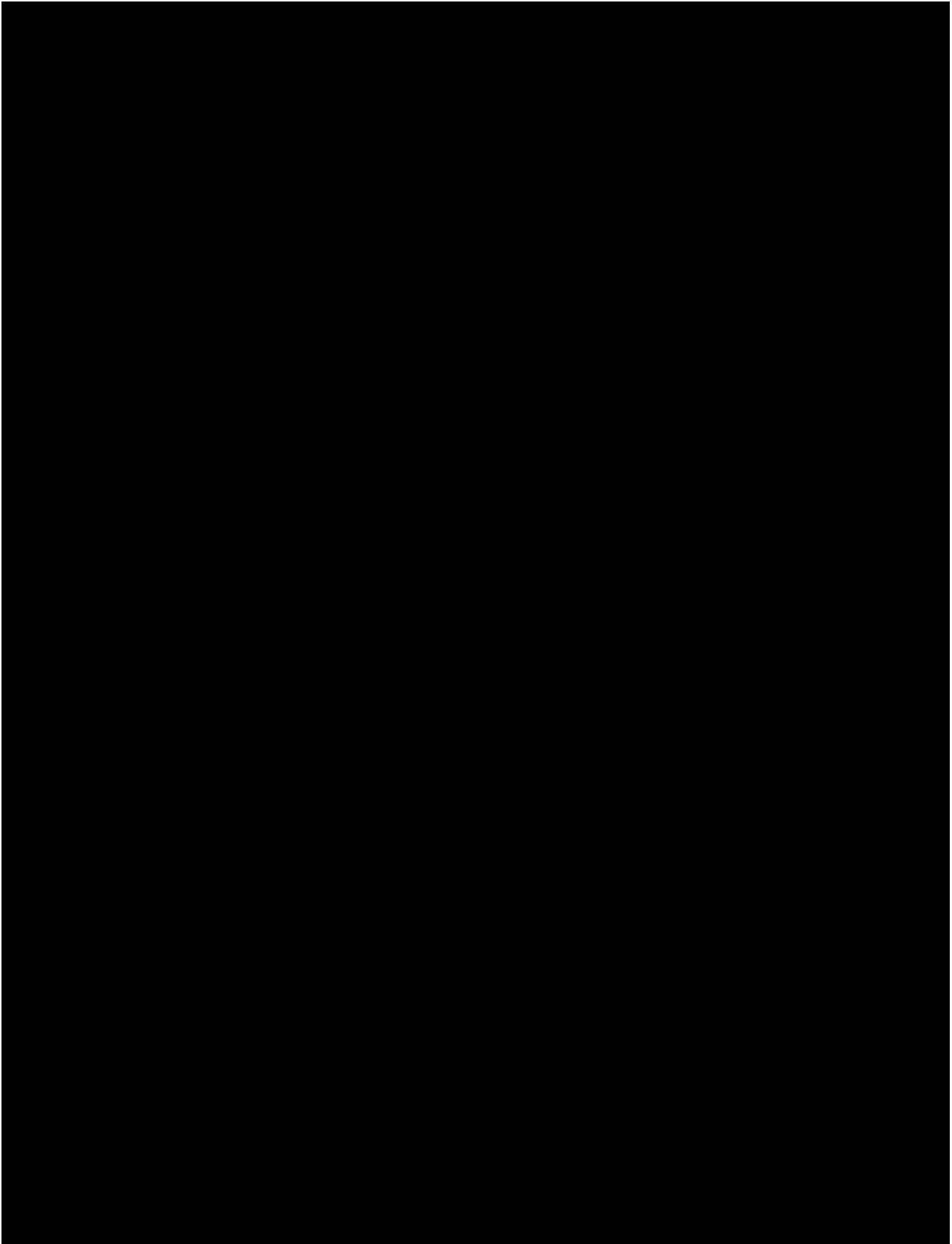


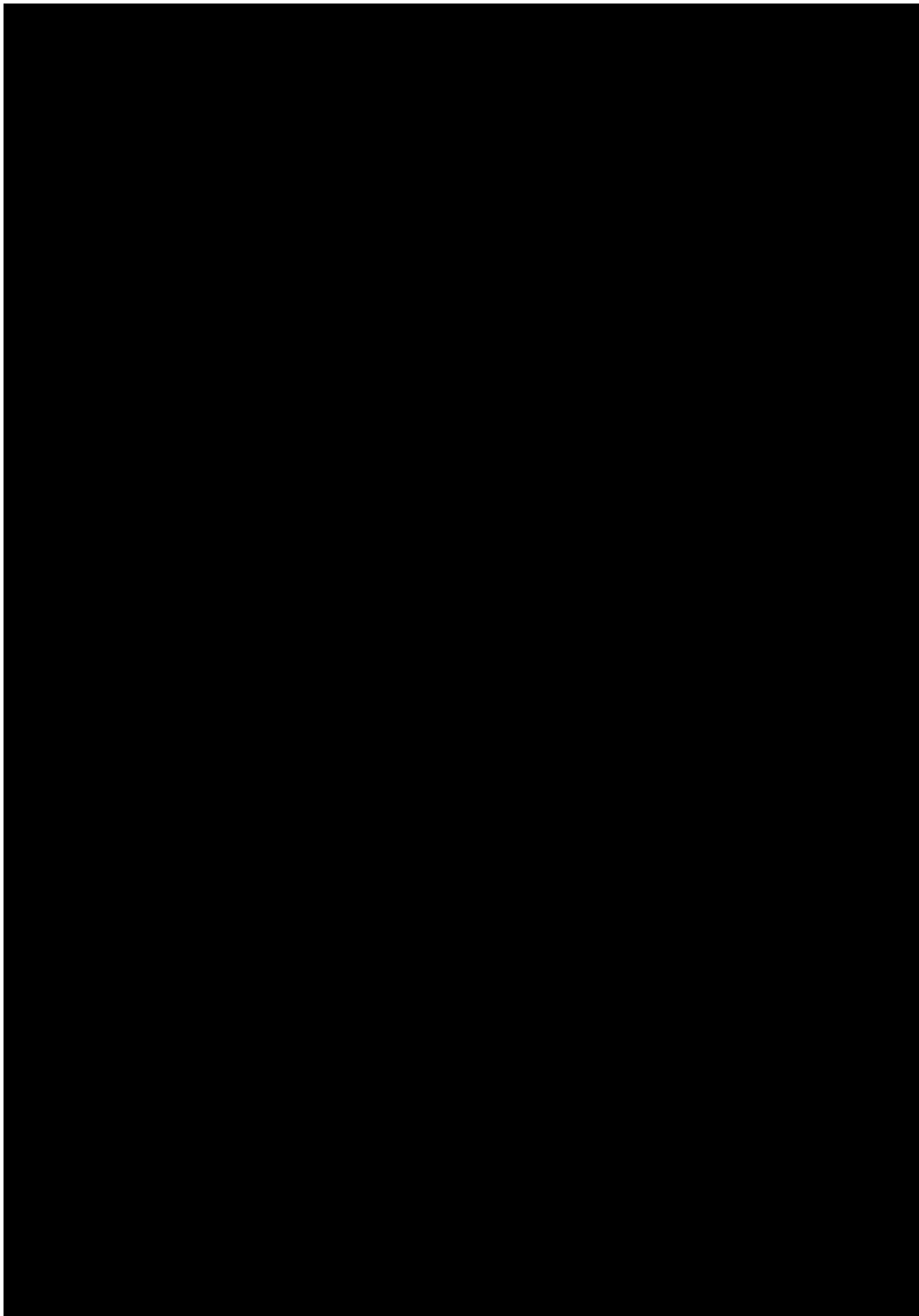
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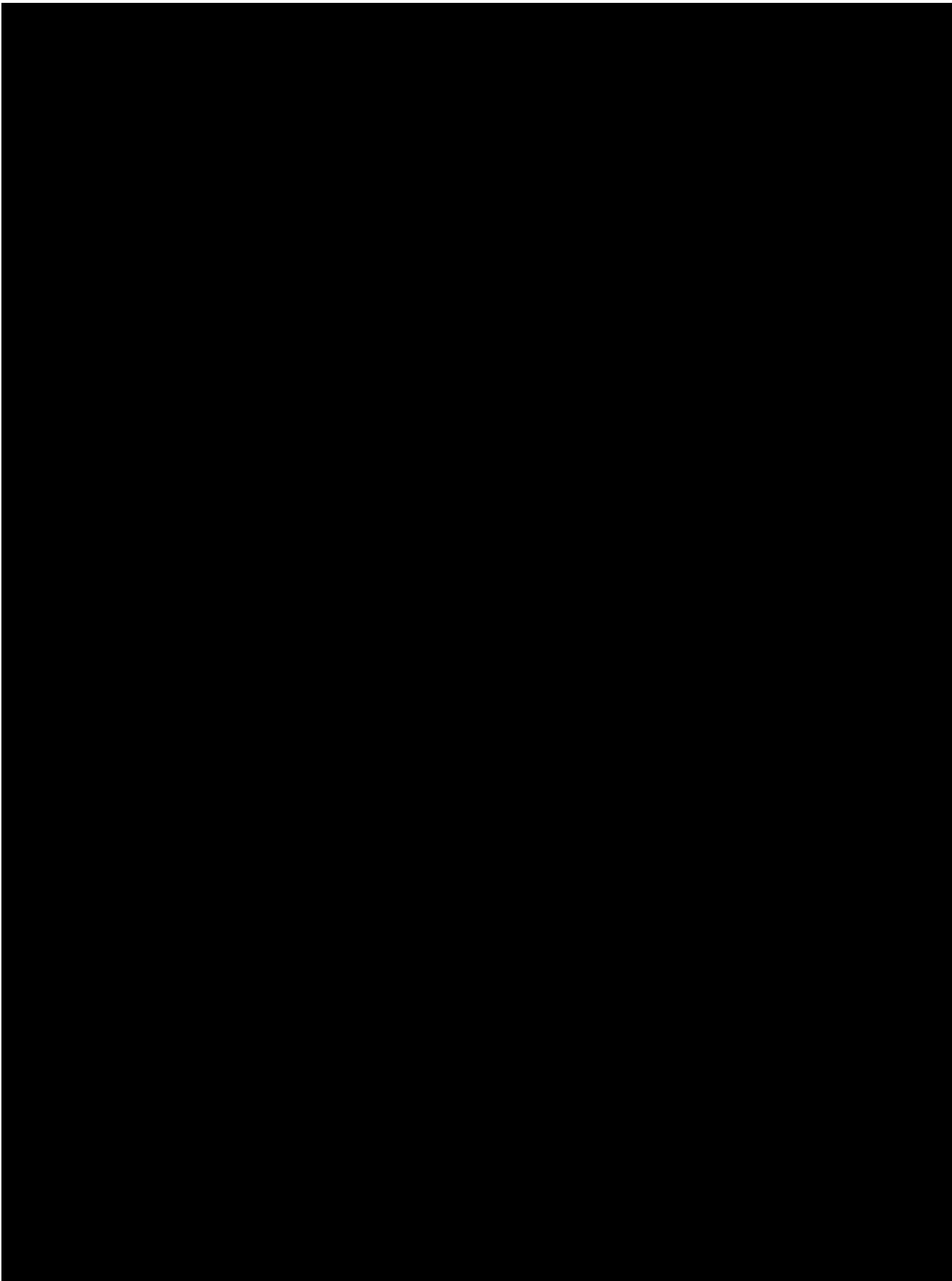
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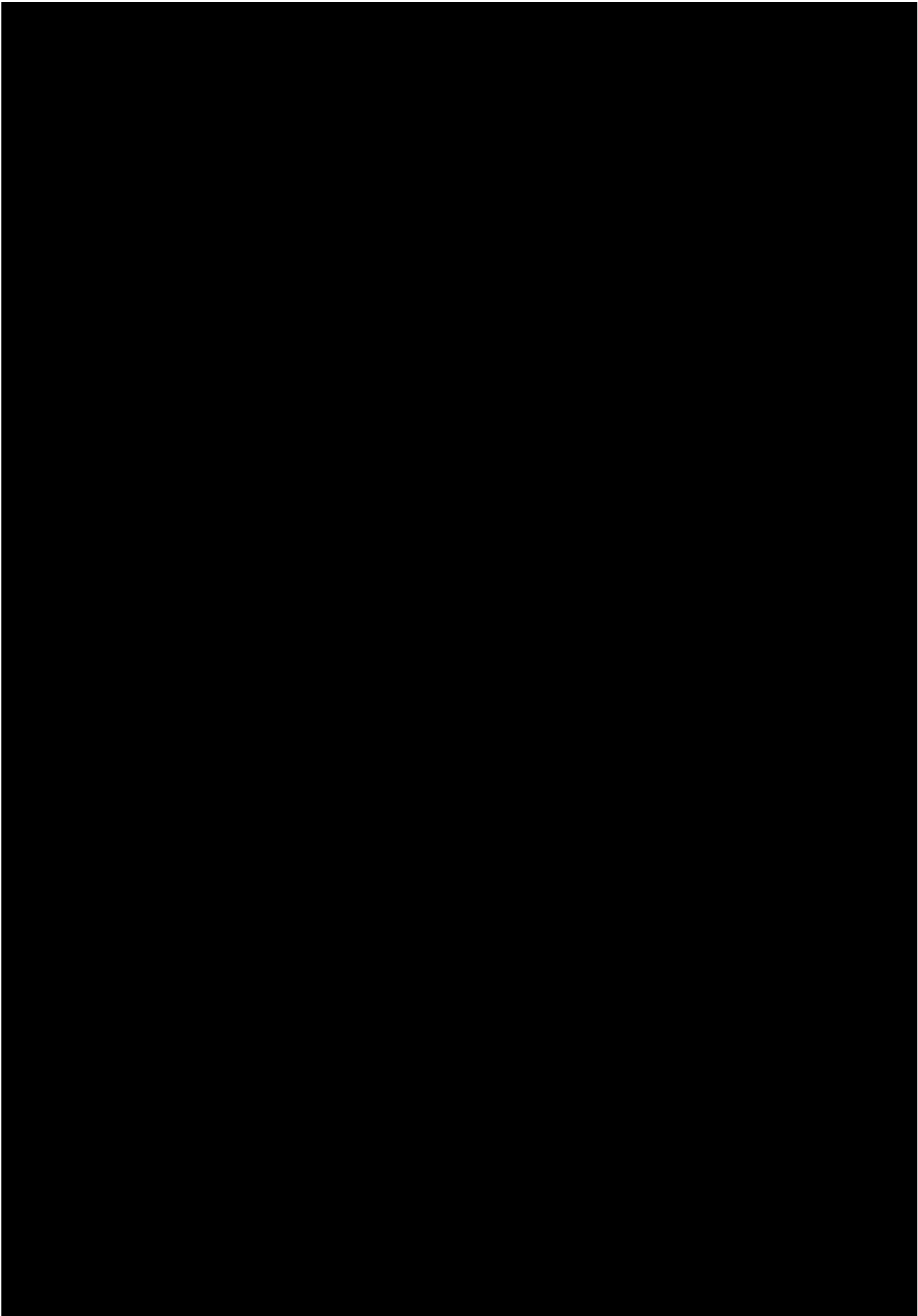








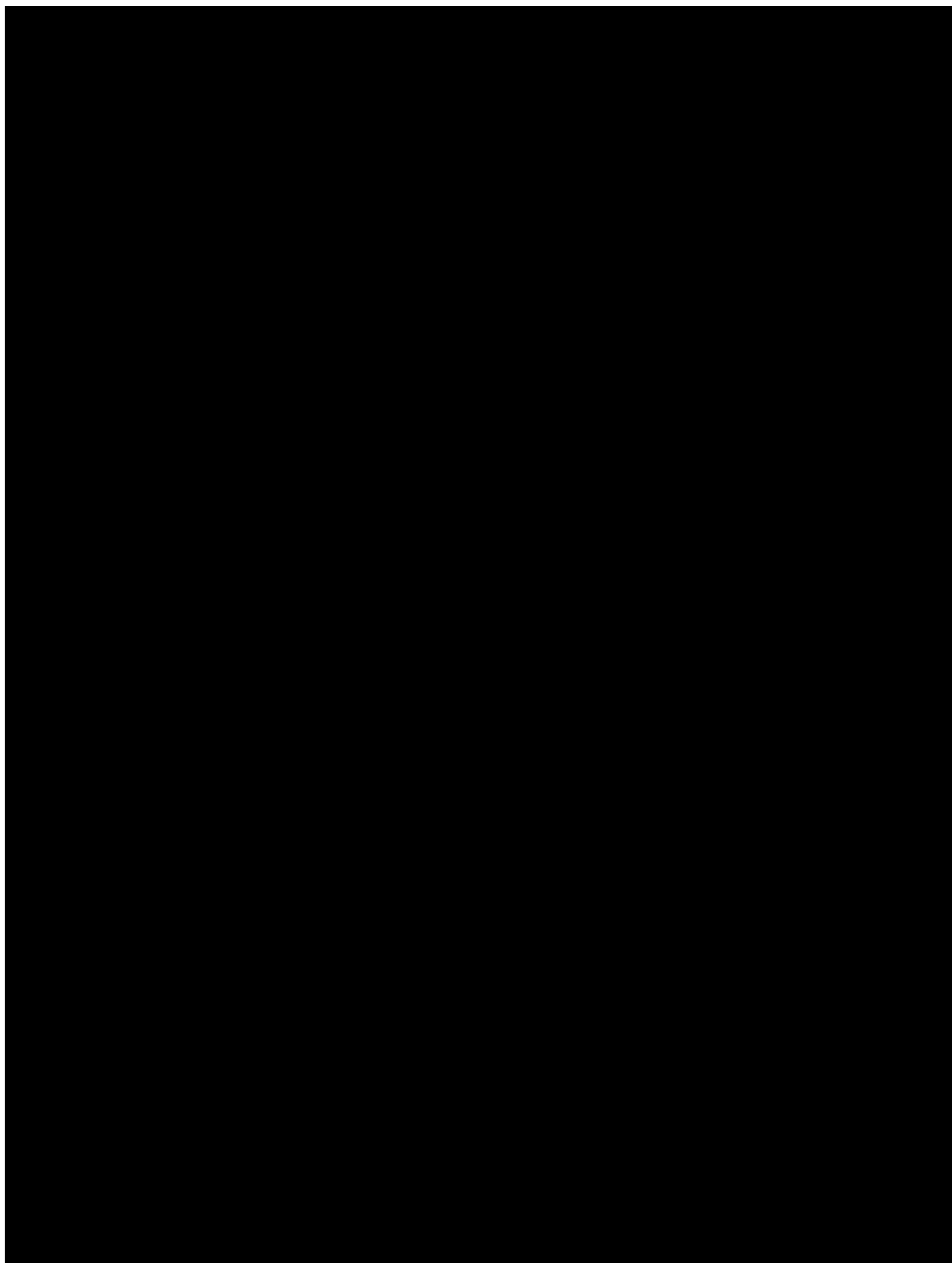




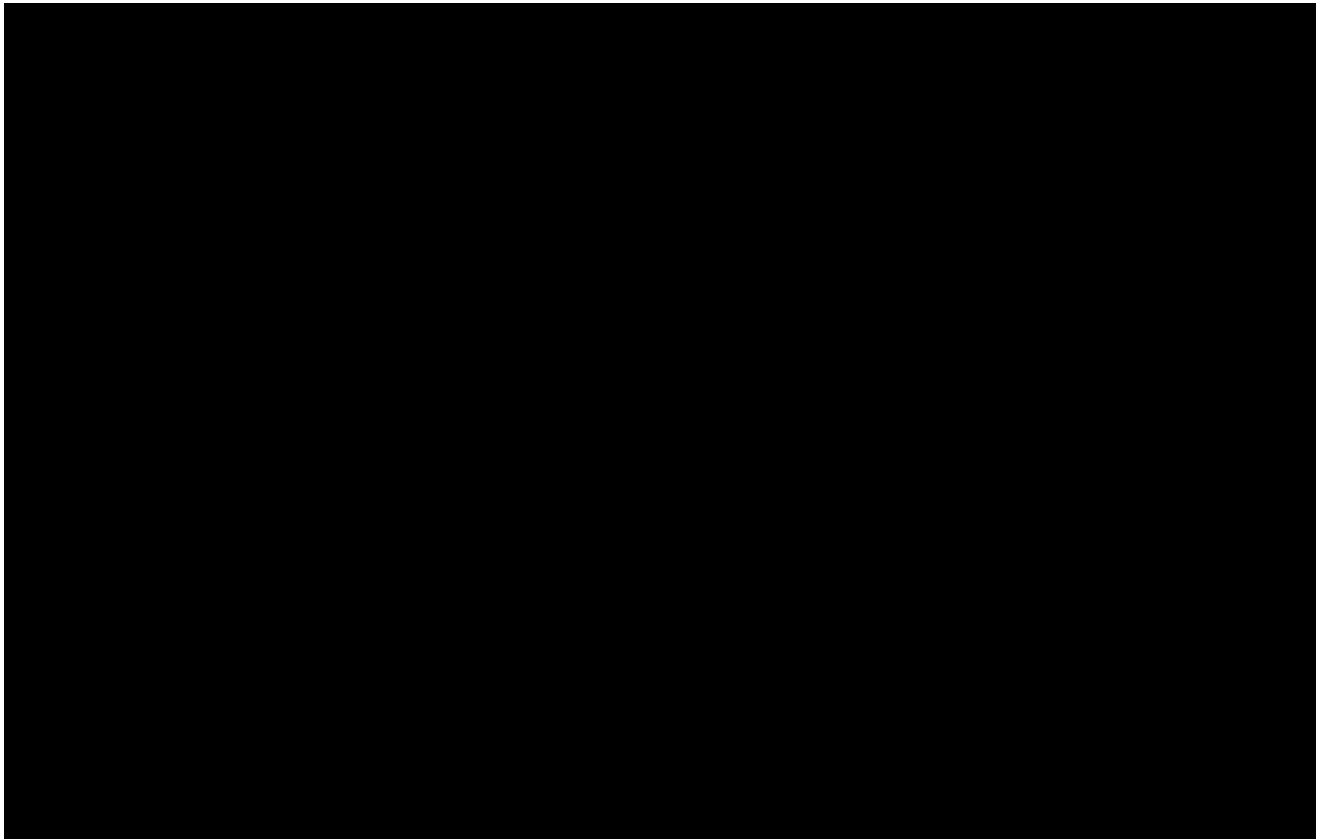


















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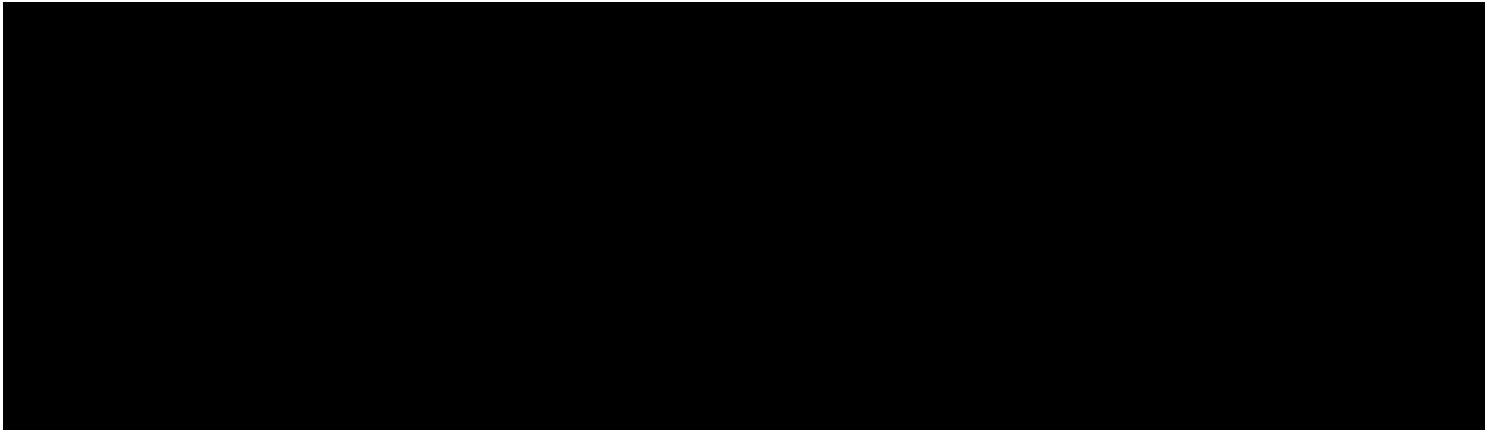
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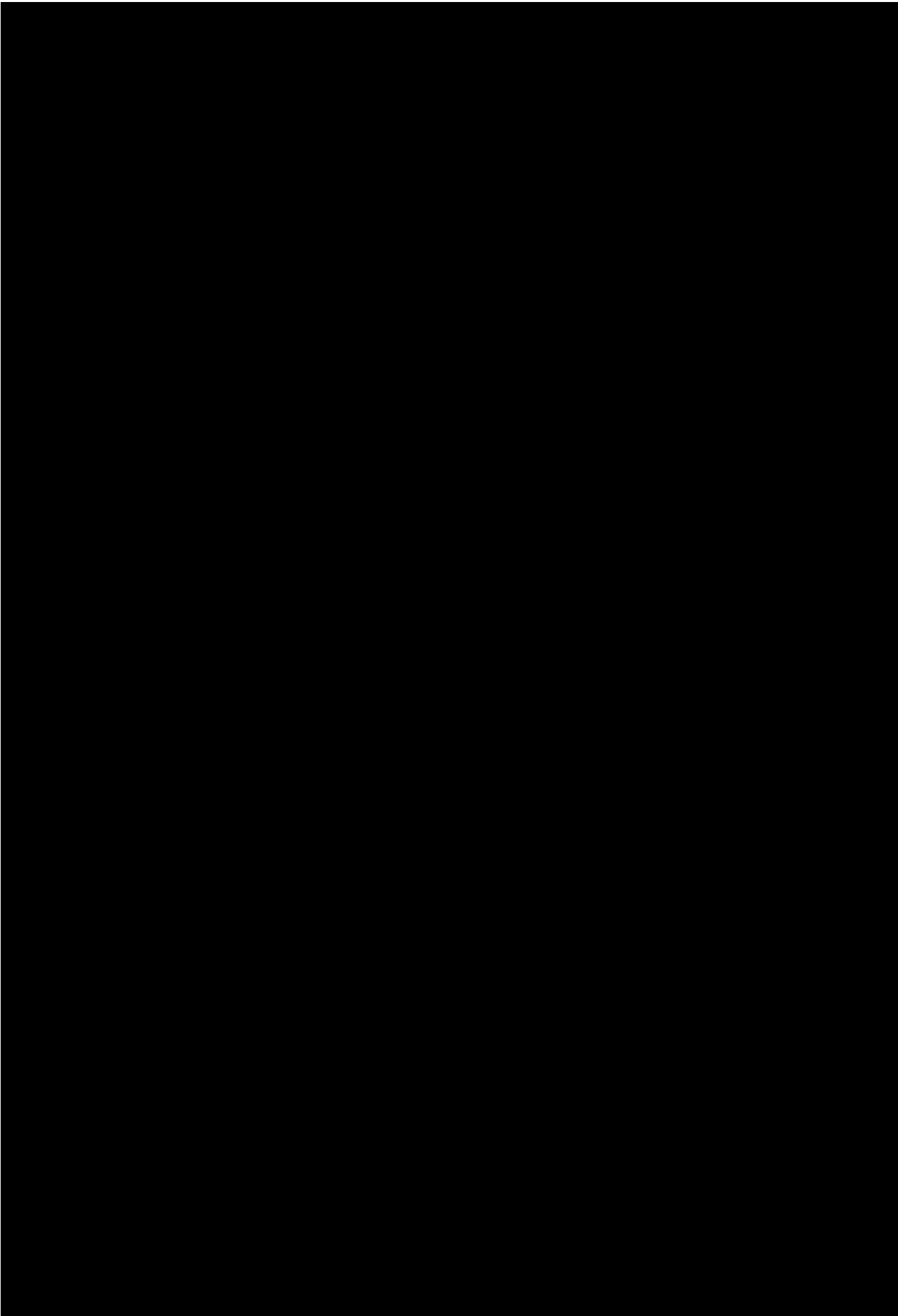


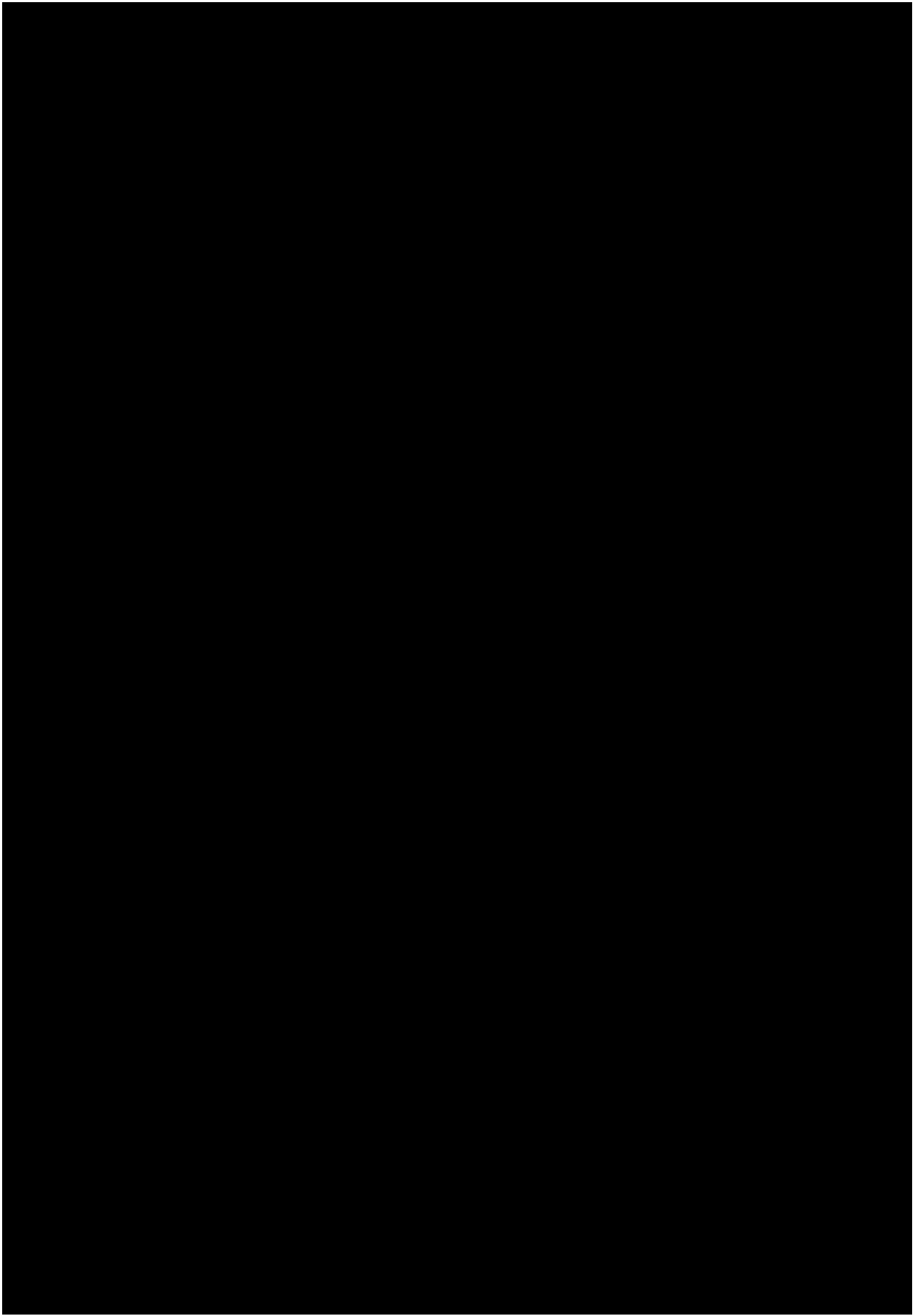




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[The following text is a dense, handwritten manuscript, likely a letter or a page from a book. It is written in a cursive script and covers the majority of the page. Due to the image quality and the nature of the handwriting, the specific words and sentences are largely illegible. The text appears to be organized into several paragraphs, with some lines indented. There are some markings that could be interpreted as punctuation or section breaks, but they are not clear enough to transcribe accurately. The overall appearance is that of a historical document or a personal correspondence.]







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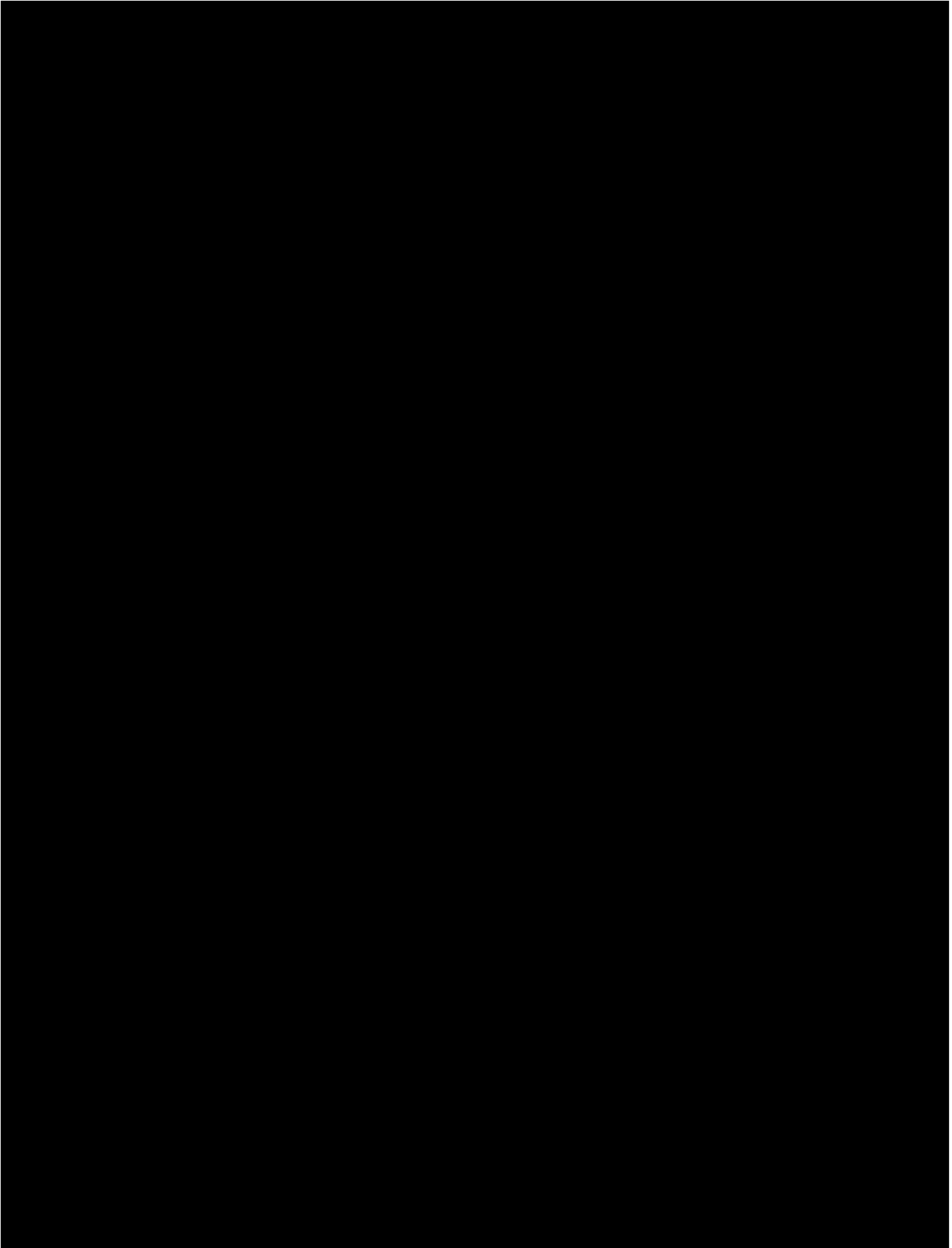
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the 1990s, the number of people in the UK who are aged 65 and over has increased by 1.5 million (1990–2000) and is projected to increase by a further 1.5 million by 2020 (Office for National Statistics 2001). The number of people aged 65 and over is projected to increase from 10.5 million in 1990 to 12.5 million in 2020, with the number of people aged 75 and over increasing from 4.5 million to 6.5 million in the same period.

There is a growing awareness of the need to develop strategies to meet the needs of the ageing population. The Department of Health (2000) has identified the need to develop a 'new paradigm' for health care, one that is based on the needs of the ageing population. This paradigm is based on the following principles:

- The need to develop a 'new paradigm' for health care, one that is based on the needs of the ageing population.
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The Department of Health (2000) has identified the need to develop a 'new paradigm' for health care, one that is based on the needs of the ageing population. This paradigm is based on the following principles:



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the 1990s, the number of people in the UK who are employed in the public sector has increased by 1.5 million, from 2.5 million in 1980 to 4 million in 1999. The public sector has become a major employer in the UK, and its growth has been a key factor in the overall growth of the economy.

The public sector has also become a major provider of social services, and its growth has been a key factor in the overall growth of the economy. The public sector has become a major provider of social services, and its growth has been a key factor in the overall growth of the economy.

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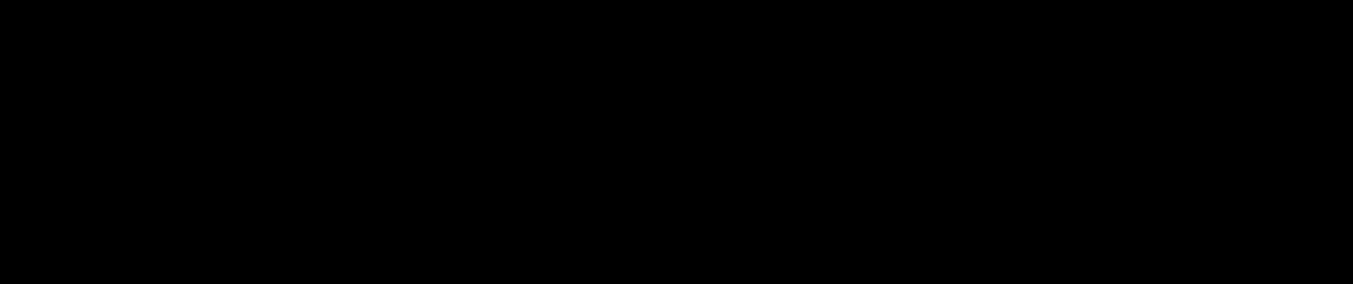
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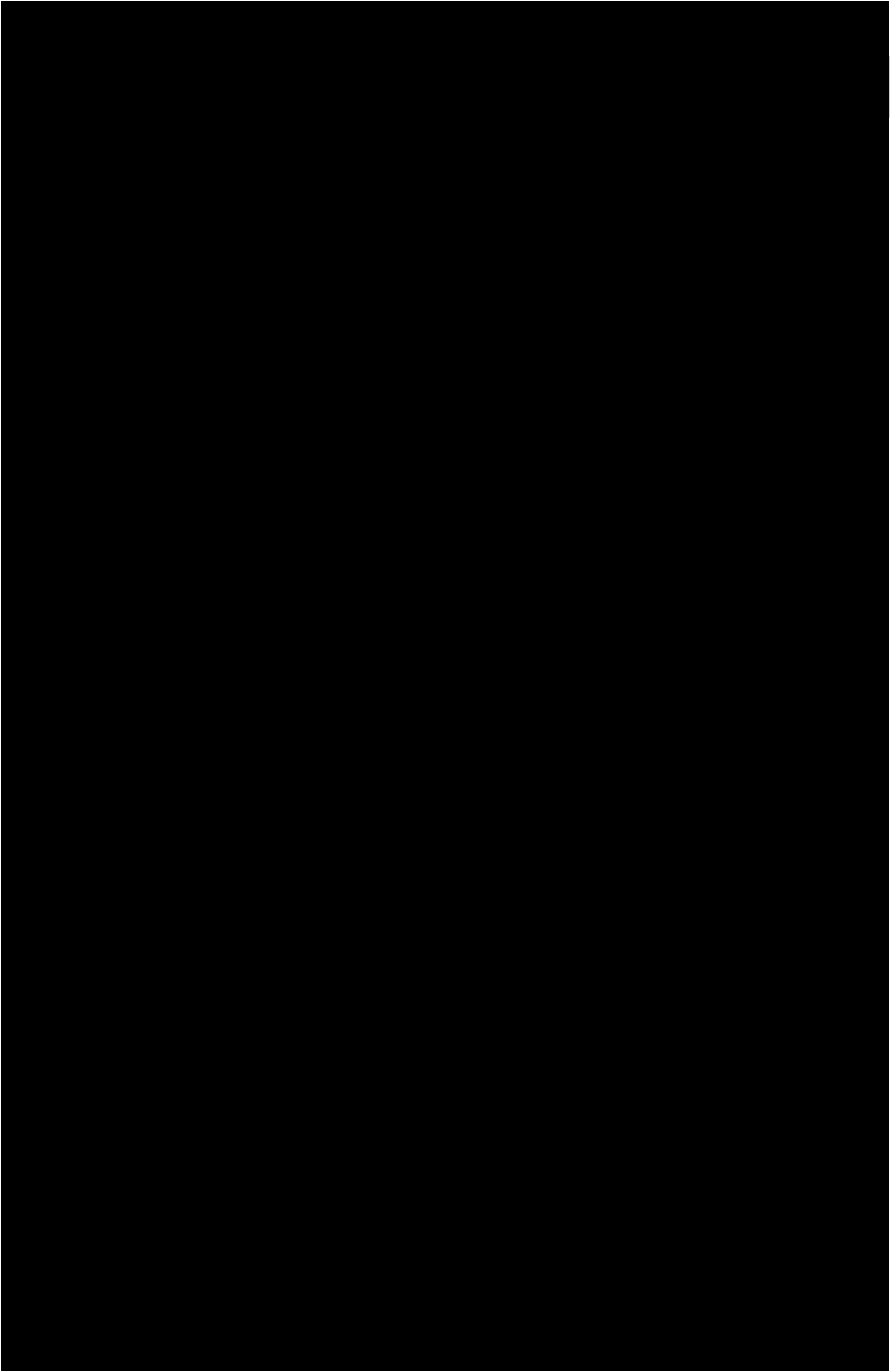
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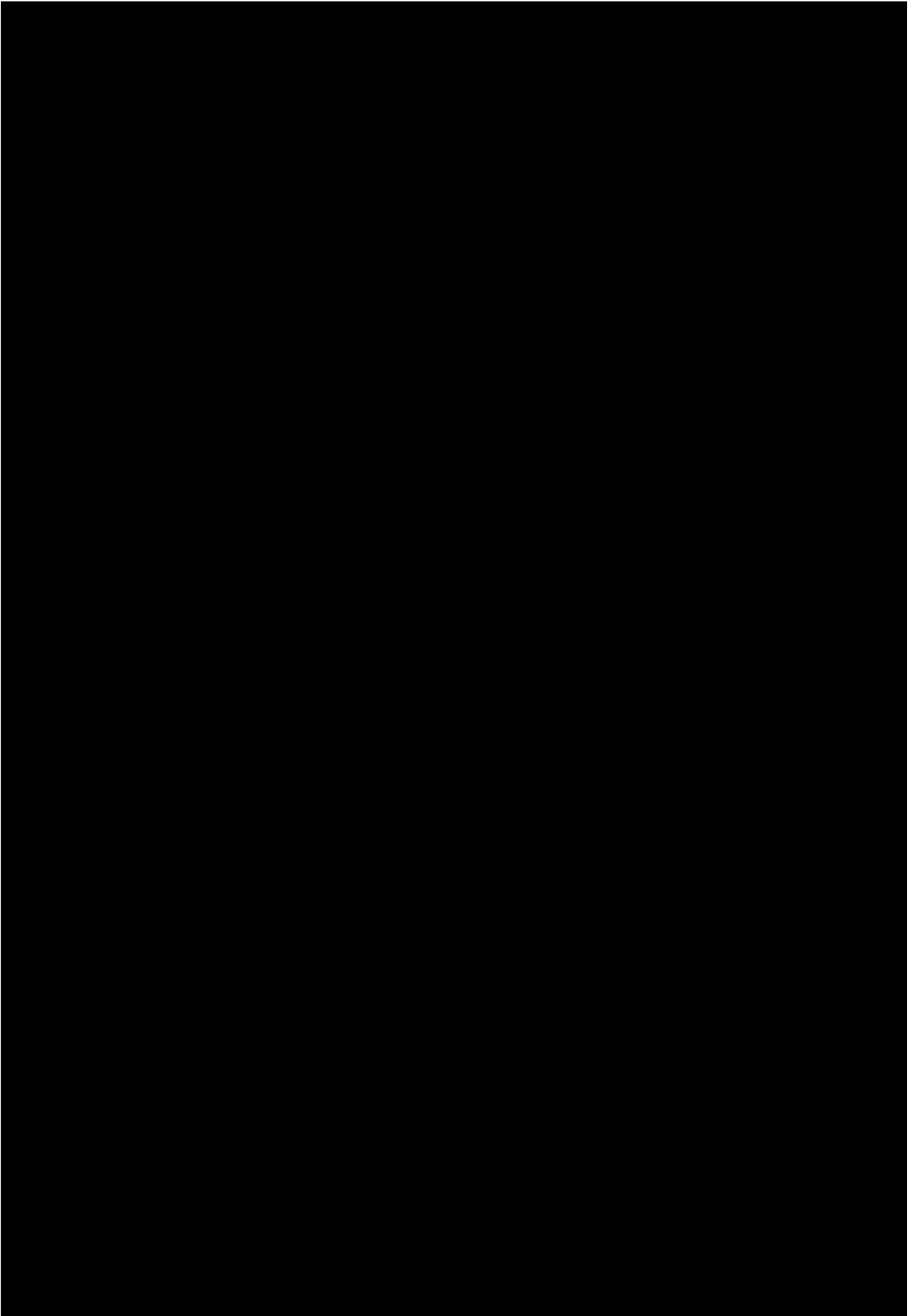












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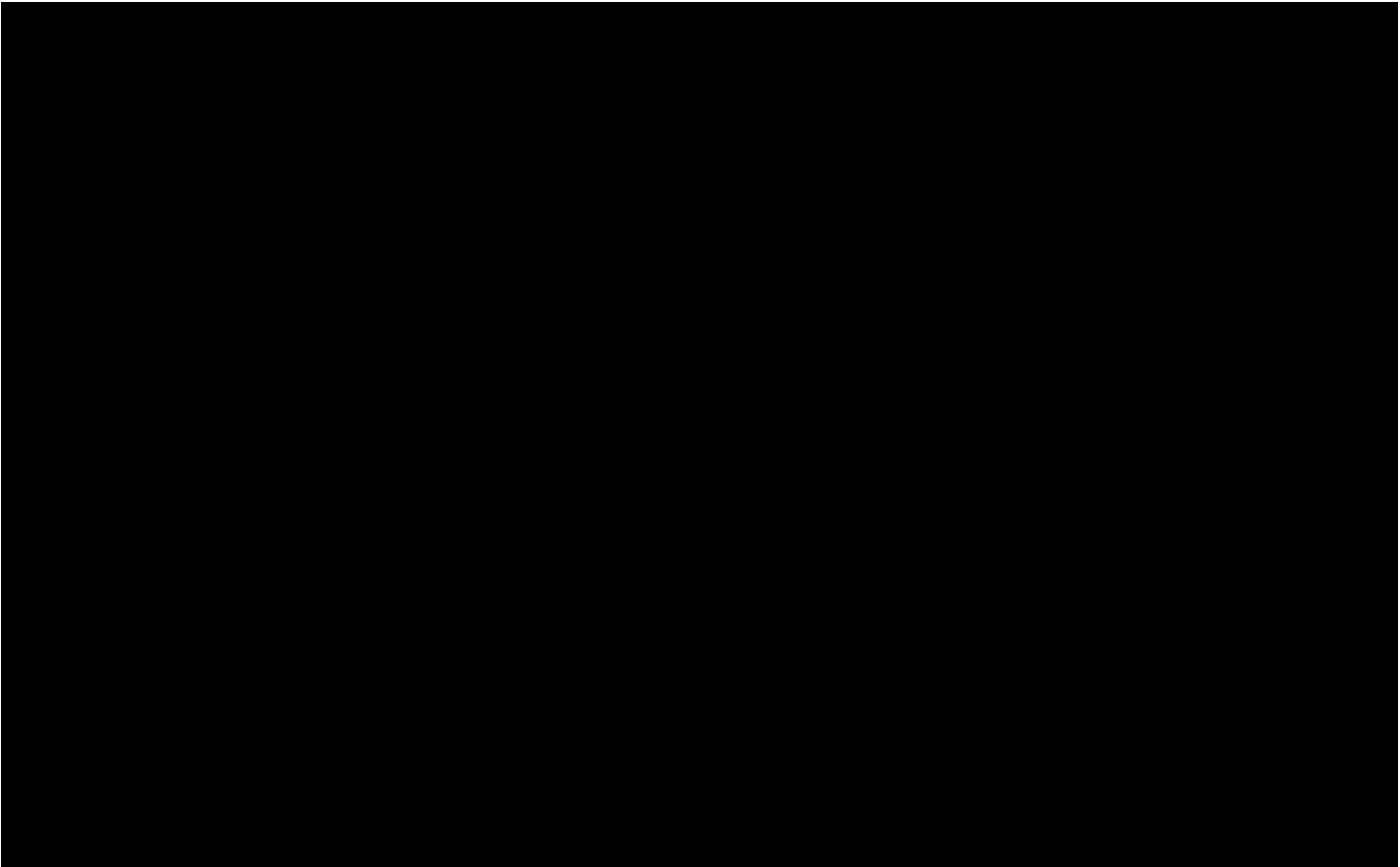
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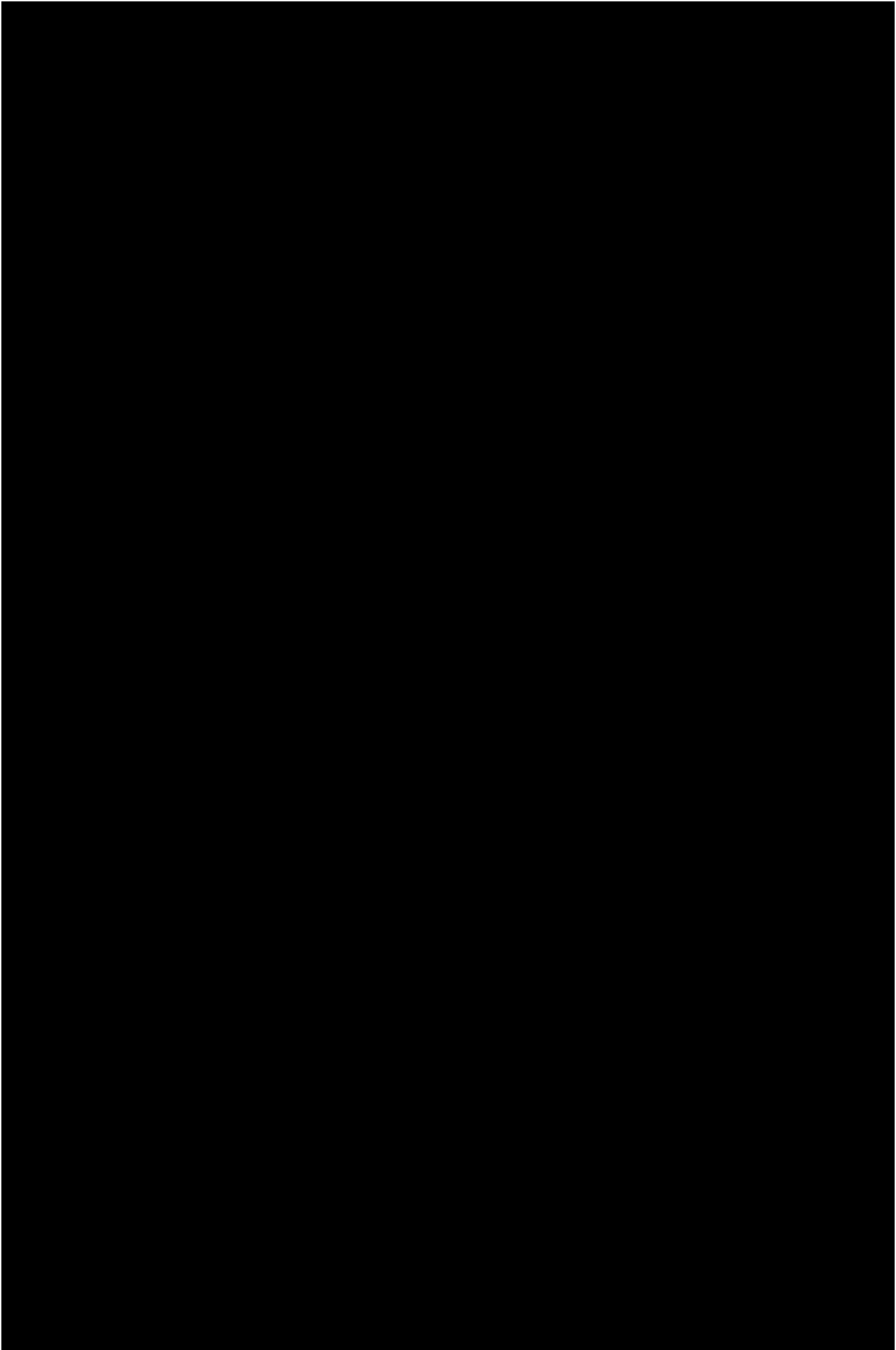
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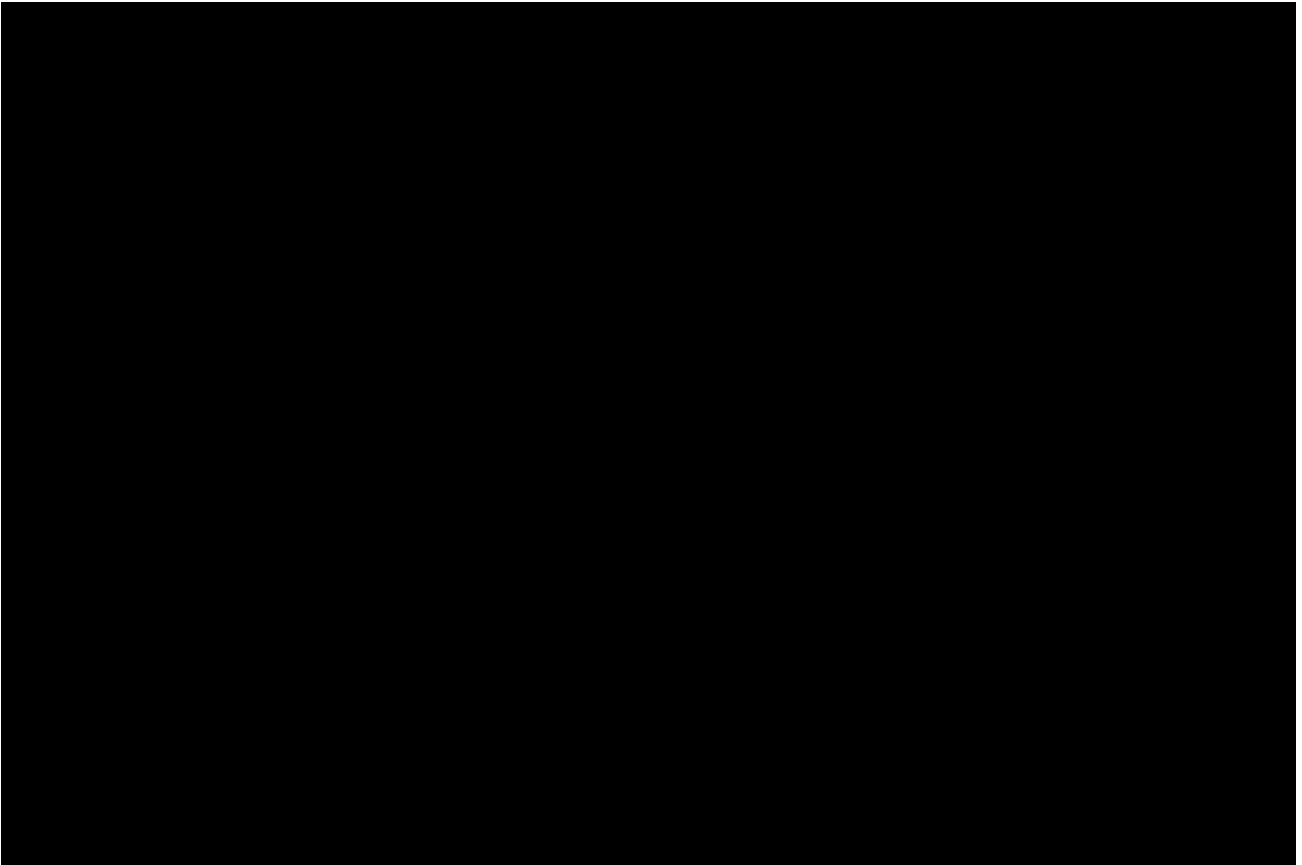
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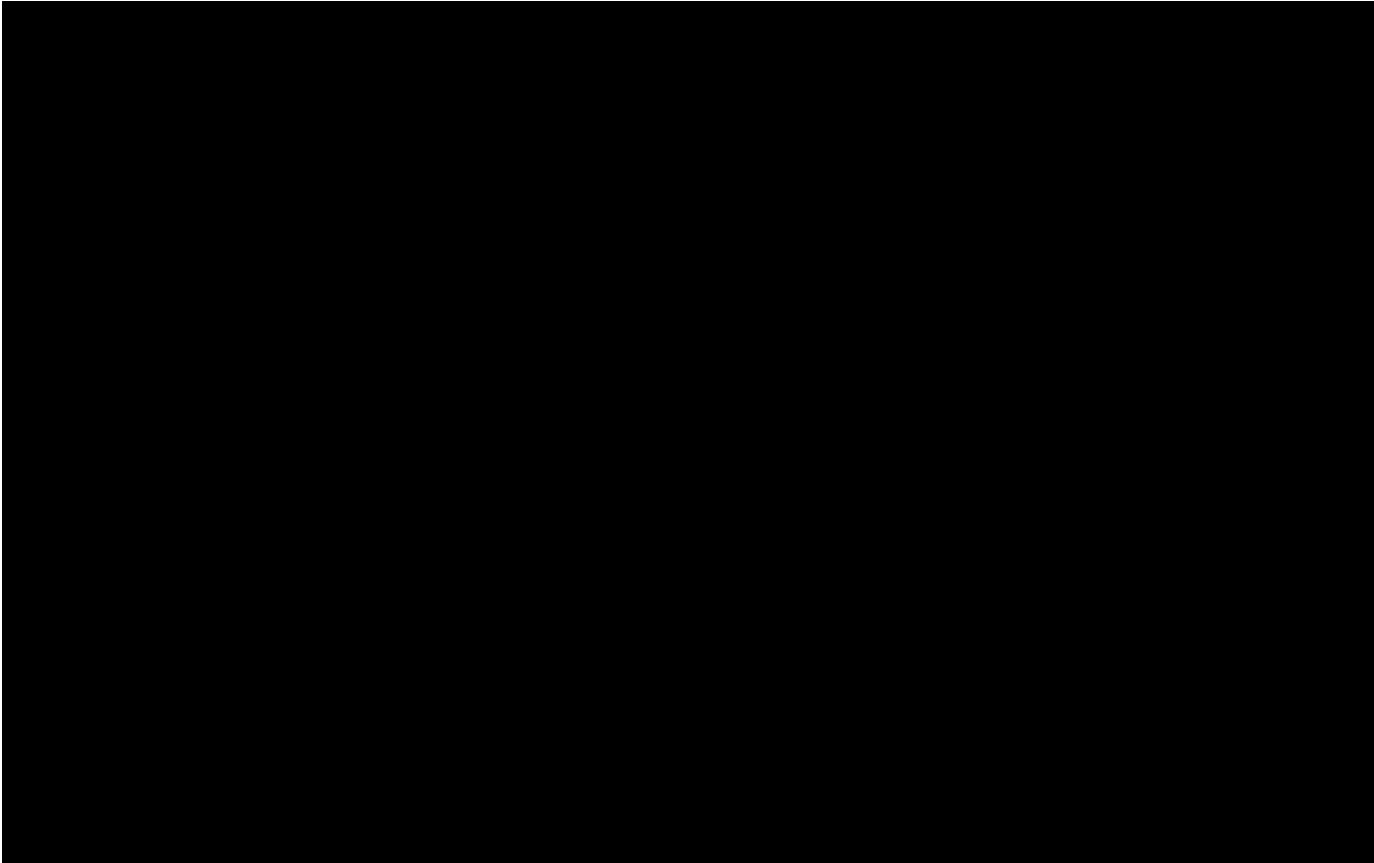
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## **SCHEDULE 2 – THE SERVICES**

### **L. Provisions Applicable to Primary Medical Services**

**Requirements relating to tailoring the Services to the characteristics of the local population are contained in the Service Specification**

## **SCHEDULE 2 – THE SERVICES**

### **M. Development Plan for Personalised Care**

**Not Applicable**



## **SCHEDULE 2 – THE SERVICES**

### **N. Health Inequalities Action Plan**

**Requirements relating to tailoring the Services to the characteristics of the local population are contained in the Service Specification**

## **SCHEDULE 3 – PAYMENT**

### **A. Aligned Payment and Incentive Rules**

<b>Not Applicable.</b>
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## **SCHEDULE 3 – PAYMENT**

### **B. Locally Agreed Adjustments to NHS Payment Scheme Unit Prices**

**Not Applicable**

## SCHEDULE 3 – PAYMENT

### C. Local Prices

1. The Commissioner will pay the Provider for the Services in accordance with this Schedule 3C.
2. Notwithstanding General Condition 1.2, the Parties expressly agree that Service Condition 36 shall only apply to and be incorporated into this Contract as follows:

<b>Sub-Conditions of Service Condition 36 which are incorporated into this Contract</b>	<b>Sub-Conditions of Service Condition 36 which are excluded from this Contract</b>
36.2	36.1
36.6	36.3 – 36.5
36.29	36.7 - 36.28 (inclusive)
36.33	36.30 – 36.32 (inclusive)
36.34	36.35

#### Definitions

3. In this Schedule 3C the following definitions are used:

<b>“Achieved”</b>	means a Milestone and/or the Outcomes (as relevant) that have been achieved by the Provider in accordance with the Achievement Criteria and <b>“Achieve”</b> and <b>“Achievement”</b> shall be construed accordingly;
<b>“Achievement Criteria”</b>	means the Digital Achievement Criteria and the Face-to-Face Achievement Criteria;
<b>“Data Output Specification”</b>	means the data output specification to be submitted by the Provider to the Commissioner in accordance with Schedule 6A;
<b>“Digital Achievement Criteria”</b>	means the criteria which must be met by the Provider in relation to a Service User being provided with the Digital Delivery Model in order to Achieve a Milestone as set out in column 3 of Table 2 of this Part 1 of this Schedule 3C;
<b>“Digital Delivery Model Price”</b>	means the maximum price per Service User (set out in Table 1 of this Part 1 of this Schedule 3C) for the provision of the Service via the Digital Delivery Model payable to the Provider when all Milestones have been Achieved;
<b>“Face-to-Face Achievement Criteria”</b>	means the criteria which must be met by the Provider in relation to a Service User being provided with the Face-to-Face Delivery Model in order to Achieve a Milestone as set out in column 2 of Table 2 of this Part 1 of this Schedule 3C;

<b>“Face to-Face Delivery Model Price”</b>	means the maximum price per Service User (set out in Table 1 of this Part 1 of this Schedule 3C) for the provision of the Service via the Face-to-Face Delivery Model payable to the Provider when all Milestones have been Achieved;
<b>“Final Episode of Engagement”</b>	has the meaning set out in section 3.2.16 of Schedule 2A (Service Specification);
<b>“Final Session”</b>	has the meaning set out in section 3.2.16 of Schedule 2A (Service Specification)
<b>“Individual Assessment”</b>	means the individual assessment following acceptance by a Service User of an invitation to participate in the Service at which a Service User is assessed in accordance with section 3.2.5 of Schedule 2A (Service Specification);
<b>“Intervention Cap”</b>	has the meaning set out in section 3.10 of Schedule 2A (Service Specification);
<b>“Intervention Period”</b>	has the meaning set out in section 3.10 of Schedule 2A (Service Specification);
<b>“Milestone”</b>	means a milestone in the provision of the Service for which payment is made as set out in Tables 1 and 2 of this Part 1 of this Schedule 3C;
<b>“Milestone Engagement Methods”</b>	means the following engagement methods: <ul style="list-style-type: none"> <li>• conversation with a health coach (via telephone or a voice over internet protocol system); or</li> <li>• exchange of messages with a health coach (with a minimum of six messages exchanged).</li> </ul>
<b>“Milestone 2 Period”</b>	means the period beginning on the Start Date and ending 12 weeks after the Start Date;
<b>“Milestone 3 Period”</b>	means the period beginning immediately after the end of the Milestone 2 Period and ending 52 weeks after the Start Date;
<b>“Minimum Episodes of Engagement”</b>	means the minimum number of episodes of engagement with a Service User to be provided in accordance with section 3.2.6 of Schedule 2A (Service Specification);
<b>“Minimum Sessions”</b>	means the minimum number of sessions with a Service User to be provided in accordance with section 3.2.6 of Schedule 2A (Service Specification);
<b>“Outcomes”</b>	means the Outcomes Achievement Criteria;
<b>“Outcomes Achievement Criteria”</b>	means the criteria which must be met by the Provider in relation to a Service User as set out in paragraph 7 of Part 1 of this Schedule 3C;
<b>“Service”</b>	means the service described in Schedule 2A (Service Specification);

**"Service Prices"** means the Face-to-Face Delivery Model Price and the Digital Delivery Model Price;

**"Start Date"** means the Monday of the week in which the Service User starts the, or participates in their, first session of, or episode of engagement within, the TDR Phase following the Individual Assessment in accordance with section 3.2.5 of Schedule 2A (Service Specification).

#### **General Principles of Payment**

4. The Provider will be paid for the Service it provides under Schedule 2A (Service Specification) subject to the Milestones and Outcomes being Achieved in accordance with Part 1 of this Schedule 3C.
5. Payments payable to the Provider under Part 1 of this Schedule 3C will be paid in accordance with Part 2 of this Schedule 3C.

## **Part 1 – Payment Calculation – Service Price**

1. Subject to paragraphs 2 and 3 of this Part 1:
  - 1.1. the Face-to-Face Delivery Model Price will be paid by the Commissioner for each Service User being provided with the Service via the Face-to-Face Delivery Model; and
  - 1.2. the Digital Delivery Model Price will be paid by the Commissioner for each Service User being provided with the Service via the Digital Delivery Model,

in staged payments depending upon Milestones Achieved by the Provider for each Service User and the Outcomes Payment will be paid by the Commissioner for each Service User which satisfies the Outcomes. The Provider will be paid monthly in arrears in respect of the staged payments for Milestones Achieved and the Outcomes Payment in accordance with Part 2 of this Schedule 3C.
2. The Provider will not be paid for any Service provided to additional Service Users who are invited to participate in the Service after the Intervention Cap has been reached. For the avoidance of doubt, once the Intervention Cap is reached, the Commissioner will continue to pay the Provider for the Service provided to existing Service Users subject to the Milestones being Achieved.
3. The Provider will not be paid for any Service provided to additional Service Users who are invited to participate in the Service after the Intervention Period has elapsed. For the avoidance of doubt, once the Intervention Period has elapsed, the Commissioner will continue to pay the Provider for the Service provided to existing Service Users who were invited to participate in the Service before the Intervention Period elapsed subject to the Milestones being Achieved.
4. The Provider will provide the Data Output Specification in accordance with Schedule 6A (Reporting Requirements) to enable the Commissioner to verify invoices submitted by the Provider to the Commissioner in accordance with Part 2 of this Schedule 3C.
5. Table 1 below shows:
  - 5.1. the Service Prices;
  - 5.2. the percentage of the Service Price payable on Achievement of each Milestone for each Service User; and
  - 5.3. the percentage of the Service Price payable on Achievement of the Outcomes for each Service User.

**Table 1**

<b>Face-to-Face Delivery Model Price</b>	[REDACTED]		
<b>Digital Delivery Model Price</b>	[REDACTED]		
<b>Milestone</b>	<b>1</b>	<b>2</b>	<b>3</b>
% of relevant Service Price payable on Achievement of Milestone	<b>30%</b>	<b>30%</b>	<b>30%</b>
<b>Outcomes Payment</b> - % of relevant Service Price payable on Achievement of Outcomes	<b>10%</b>		

6. Table 2 below shows the Achievement Criteria at each Milestone for the Service provided via the Face-to-Face Delivery Model and the Digital Delivery Model, to be Achieved by the Provider for each Service User (as applicable).

**Table 2 – Milestones for Digital Delivery Model**

<b>Milestone</b>	<b>Face-to-Face Achievement Criteria</b>	<b>Digital Achievement Criteria</b>
Milestone 1	<p>All of the following criteria have been fulfilled:</p> <ul style="list-style-type: none"> <li>(1) the Individual Assessment has been provided to the Service User by the Provider;</li> <li>(2) the Provider has in writing from the referrer confirmation of the specific medication changes which are required (or that no medication changes are required) and the Provider has ensured that prior to the first day of the TDR Phase, the Service User understands the medication changes to take</li> </ul>	<p>All of the following criteria have been fulfilled:</p> <ul style="list-style-type: none"> <li>(1) the Service User has registered for the Service or created a digital account (as relevant);</li> <li>(2) the Individual Assessment has been provided to the Service User by the Provider;</li> <li>(3) the Provider has in writing from the referrer confirmation of the specific medication changes which are required (or that no medication changes are required) and the Provider has ensured that prior to the first day of the TDR Phase, the Service User understands the medication changes to take place (or that no medication changes are required);</li> </ul>

<sup>5</sup> Successful bidder's Face-to-Face Delivery Model Price to be inserted here prior to contract award.

<sup>6</sup> Successful bidder's Digital Delivery Model Price to be inserted here prior to contract award.



	<p>place (or that no medication changes are required);</p> <p>(3) the the Service User has started the TDR Phase and the first of the Minimum Sessions has been provided to the Service User by the Provider;</p> <p>(4) valid weight and blood glucose measurements (and blood pressure measurements if applicable) for the Service User have been taken in accordance with section 3.2.17 of Schedule 2A (Service Specification) and reported in accordance with Schedule 6A; and</p> <p>(5) the Data Output Specification has been submitted by the Provider to the Commissioner in accordance with Schedule 6A in relation to the Service User.</p>	<p>(4) the Service User has started the TDR Phase and the first of the Minimum Episodes of Engagement using at least one of the Milestone Engagement Methods has been provided to the Service User by the Provider;</p> <p>(5) valid weight and blood glucose measurements (and blood pressure measurements if applicable) for the Service User has been taken in accordance with section 3.2.17 of Schedule 2A (Service Specification) and reported in accordance with Schedule 6A; and</p> <p>(6) the Data Output Specification has been submitted by the Provider to the Commissioner in accordance with Schedule 6A in relation to the Service User.</p>
Milestone 2	<p>All of the following criteria have been fulfilled:</p> <p>(1) the Milestone 2 Period has elapsed;</p> <p>(2) the Service User has attended at least six of the eight Minimum Sessions within the Milestone 2 Period;</p> <p>(3) valid weight and blood glucose measurements (and blood pressure measurements if applicable) for the Service User have been taken for each session attended by the Service User in accordance with section 3.2.17 of Schedule 2A (Service Specification) and reported in accordance with Schedule 6A; and</p> <p>(4) the Data Output Specification has been submitted by the Provider to the Commissioner in accordance with Schedule 6A in relation to the Service User.</p>	<p>All of the following criteria have been fulfilled:</p> <p>(1) the Milestone 2 Period has elapsed;</p> <p>(2) there is a time stamped record that the Service User has logged into the Service within the Milestone 2 Period;</p> <p>(3) the Service User has participated in at least eight of the Minimum Episodes of Engagement using at least one of the Milestone Engagement Methods within the Milestone 2 Period;</p> <p>(4) valid weight and blood glucose measurements (and blood pressure measurements if applicable) for the Service User have been taken, for each of the Minimum Episodes of Engagement that the Service User has participated in in accordance with section 3.2.17 of Schedule 2A (Service Specification) and reported in accordance with Schedule 6A; and</p> <p>(5) the Data Output Specification has been submitted by the Provider to the Commissioner in accordance with Schedule 6A in relation to the Service User.</p>
Milestone 3	<p>All of the following criteria have been fulfilled:</p> <p>(1) the Milestone 3 Period has elapsed;</p>	<p>All of the following criteria have been fulfilled:</p> <p>(1) the Milestone 3 Period has elapsed;</p>

	<p>(2) the Service User has attended at least seven of the twelve Minimum Sessions within the Milestone 3 Period and one of those Minimum Sessions was the Final Session;</p> <p>(3) valid weight and blood glucose measurements (and blood pressure measurements if applicable) for the Service User have been taken for each session attended by the Service User in accordance with section 3.2.17 of Schedule 2A (Service Specification) and reported in accordance with Schedule 6A; and</p> <p>(4) the Data Output Specification has been submitted by the Provider to the Commissioner in accordance with Schedule 6A in relation to the Service User.</p>	<p>(2) there is a time stamped record that the Service User has logged into the Service within the Milestone 3 Period;</p> <p>(3) the Service User has participated in at least seven of the Minimum Episodes of Engagement using at least one of the Milestone Engagement Methods within the Milestone 3 Period and one of those Minimum Episodes of Engagement was the Final Episode of Engagement;</p> <p>(4) valid weight and blood glucose measurements (and blood pressure measurements if applicable) for the Service User have been taken, for each of the Minimum Episodes of Engagement that the Service User has participated in, in accordance with section 3.2.17 of Schedule 2A (Service Specification) and reported in accordance with Schedule 6A; and</p> <p>(5) the Data Output Specification has been submitted by the Provider to the Commissioner in accordance with Schedule 6A in relation to the Service User.</p>
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7. To Achieve the Outcomes for each Service User:

- 7.1. all of the Service User's weight measurements at 0, 3, 6 and 12 months must have been taken in accordance with section 3.2.17 of Schedule 2A (Service Specification) and reported in accordance with Schedule 6A; and
- 7.2. the recorded weight of the Service User at the Final Session or the Final Episode of Engagement (as relevant) must indicate a weight loss of at least 10% of the weight recorded at Milestone 1.

8. The Commissioner shall determine whether or not the Provider has Achieved a Milestone or the Outcomes in accordance with the reports submitted by the Provider in accordance with Schedule 6A (Reporting Requirements) (including the Data Output Specifications submitted).
9. For the avoidance of doubt, the Provider will not be entitled to any increase to the Service Price during the Contract Term to account for inflation, indexation or any other factor which may increase the Provider's costs of delivering the Service.
10. The Commissioner may deduct from any payments due to the Provider under this Part 1 of Schedule 3C any sums that the Commissioner is entitled to withhold or retain in accordance with Part 2 of Schedule 4 (Local Quality Requirements). If the Commissioner exercises its right to make such deductions, the Commissioner may deduct such sum from the amount payable under the applicable invoice issued by the Provider. If the amount due under the applicable invoice has been paid before the applicable deduction has been applied, the Commissioner may require the Provider to repay such amount that it would have been entitled to deduct or the Commissioner may deduct such amount from any subsequent invoice. Any sums that are withheld by the Commissioner that are subsequently to be paid to the Provider in accordance with Part 2 of Schedule 4 (Local Quality Requirements) shall be included in the next invoice issued by the Provider in accordance with Part 2 of this Schedule 3C.

## **Part 2 – Invoicing Process**

1. The Commissioner uses an online service provided by Tradeshift Network Ltd of 55 Baker Street London W1U 7EU found online at [www.tradeshift.com](http://www.tradeshift.com) (“Tradeshift”) as its online platform for receiving invoices. The Provider will create an online account with Tradeshift from the Effective Date for the purpose of submitting electronic invoices to the Commissioner in accordance with this Part 2 of this Schedule 3C.
2. The Provider will utilise one of the integration options provided by Tradeshift in order to deliver electronic invoices to the Commissioner.
3. The Provider shall:
  - 3.1. comply with the technical requirements of Tradeshift including any changes to such requirements that may be required by Tradeshift from time to time; and
  - 3.2. ensure that all electronic invoices are received by the Commissioner in accordance with the timescales set out in this Part 2 of Schedule 3C.
4. The Provider shall be responsible for its relationship with Tradeshift at all times.
5. Prior to uploading invoices to Tradeshift, the Provider will submit an electronic invoice to the Commissioner in accordance with paragraphs 1-4 of this Part 2 within 10 Operational Days after the end of the month in which a Milestone and/or the Outcomes have been Achieved for a Service User setting out the payment due to the Provider.
6. Following submission of an invoice in accordance with paragraphs 1-5 of this Part 2, the Commissioner will consider and verify the invoice as against the Data Output Specifications provided by the Provider in accordance with Schedule 6A for the relevant month within 20 days of receipt of the invoice.
7. If the Commissioner is unable to verify an invoice in accordance with paragraph 6, the Commissioner will request that the Provider submits a revised electronic invoice in accordance with paragraph 1 above. Paragraph 6 above shall then apply in respect of the Commissioner’s verification of the revised invoice.
8. The final invoice will be verified by agreement between the Commissioner (including any representative acting on behalf of the Commissioner) and the Provider, and if the parties do not verify the invoice paragraph 6 above shall apply.
9. Subject to paragraph 10 of Part 2 of this Schedule 3C, the Commissioner will pay the Provider any sums due under an invoice no later than 30 days from the date on which the Commissioner determines that the invoice is valid and undisputed in accordance with paragraph 6.
10. The Parties agree that paragraph 10 of Part 1 of this Schedule 3C shall apply in relation to breaches of thresholds of the Local Quality Requirements as set out in Schedule 4 (Local Quality Requirements).
11. Where any Party disputes any sum to be paid by it then a payment equal to the sum not in dispute shall be paid and the dispute as to the sum that remains unpaid shall be determined in accordance with General Condition 14. Provided that the sum has been disputed in good faith, Interest due on any sums in dispute shall not accrue until the date falling 5 Operational Days after resolution of the dispute between the Parties.
12. For the avoidance of doubt, Service Condition 36.47 (Set Off) shall apply.
13. The Provider will maintain complete and accurate records of, and supporting documentation for, all amounts which may be chargeable to the Commissioner pursuant to this Contract. Such records shall be retained for inspection by the Commissioner for 6 years from the end of the Contract Year to which the records relate.

**SCHEDULE 3 – PAYMENT**

**D. Expected Annual Contract Values**

Not Applicable
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**SCHEDULE 3 – PAYMENT**

**E. Timing and Amounts of Payments in First and/or Final Contract Year**

<b>Not Applicable</b>
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**SCHEDULE 3 – PAYMENT**

**F. CQUIN**

<b>Not Applicable</b>
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## **SCHEDULE 4 – LOCAL QUALITY REQUIREMENTS**

### **Part 1**

Quality Requirement	Method of Measurement and Thresholds	Consequence of Breach	Period over which the Requirement is to be achieved
<b>KPI 1 Component: Data Quality</b>  The Provider shall comply with the reporting requirements set out in the Data Output Specification detailed in Annex 2 of Schedule 6A. This includes the monthly reporting of particulars related to Service Users' attendance on the programme. This is to be done to the level of detail, format and quality prescribed in the "Data Output Specifications" document and the "Data Format Specification" document. These are set out in Annexes 2 and 3, respectively, of Schedule 6A and are together referred to, in this Schedule 4C, as the "Data Specifications".	KPI 1a: The proportion of Service User data records at referral that are recorded in line with the Data Specifications. <ul style="list-style-type: none"> <li>100% - <b>"Target"</b></li> <li>Between 95% and 99.9% <b>"Mid Threshold"</b></li> <li>&lt;95% - <b>"Lower Threshold"</b></li> </ul>	As set out in Part 2 of this Schedule 4 (Local Quality Requirements)	Monthly
	KPI 1b: The proportion of Service Users' data records at Individual Assessment that are recorded in line with the 'Outcome' fields in the Data Specifications. <ul style="list-style-type: none"> <li>100% - <b>"Target"</b></li> <li>Between 95% and 99.9% <b>"Mid Threshold"</b></li> <li>&lt;95% - <b>"Lower Threshold"</b></li> </ul>	As set out in Part 2 of this Schedule 4 (Local Quality Requirements)	Monthly
	KPI 1c: The proportion of Service Users' data records at Individual Assessment that are recorded in line with the 'Demographic' fields in the Data Specifications. <ul style="list-style-type: none"> <li>100% - <b>"Target"</b></li> <li>Between 95% - and 99.9% <b>"Mid Threshold"</b></li> <li>&lt;95% - <b>"Lower Threshold"</b></li> </ul>	As set out in Part 2 of this Schedule 4 (Local Quality Requirements)	Monthly
	KPI 1d: The proportion of Service Users' data records at Individual Assessment that are recorded in line with the 'Administration' fields in the Data Specifications. <ul style="list-style-type: none"> <li>100% - <b>"Target"</b></li> <li>Between 95% -and 99.9% <b>"Mid Threshold"</b></li> <li>&lt;95% - <b>"Lower Threshold"</b></li> </ul>	As set out in Part 2 of this Schedule 4 (Local Quality Requirements)	Monthly



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	<p>KPI 1e: The proportion of Service Users' weight fields that are recorded in line with the Data Specifications.</p> <ul style="list-style-type: none"> <li>• 100% - <b>“Target”</b></li> <li>• Between 95% -and 99.9% <b>“Mid Threshold”</b></li> <li>• &lt;95% - <b>“Lower Threshold”</b></li> </ul> <p>For Service Users on the Face-to-Face Delivery Model weight measurements are recorded for each session. For Service Users on the Digital Delivery Model, weight measurement requirements are set out in Schedule 3C.</p>	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Monthly</p>
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<b>KPI 2 Component: Eligibility</b>	<p>KPI 2: The proportion of Service Users starting the first episode of engagement of the TDR Phase that meet the eligibility criteria at referral as defined in Schedule 2A (Service Specification)</p> <ul style="list-style-type: none"> <li>• 100% - <b>“Target”</b></li> </ul>	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Monthly</p>
<b>KPI 3 Component: Uptake</b> The Provider will be required to report on the KPIs requirements listed under this component allowing sufficient time for Service Users to have attended the specified number of sessions. Provider performance against KPI 3 and KPI 4 will be reviewed as part of the Quarterly Contract Review Meetings.	<p>KPI 3a: The proportion of eligible Service Users who have attended the Individual Assessment (where 3 months has elapsed since the date of referral).</p> <ul style="list-style-type: none"> <li>• ≥85% - <b>“Target”</b></li> <li>• Between 75% - 84.9% - <b>“Mid Threshold”</b></li> <li>• &lt;75% - <b>“Lower Threshold”</b></li> </ul>	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>
	<p>KPI 3b: The proportion of eligible Service Users who have commenced TDR through either the Face-to-Face Delivery Model or the Digital Delivery Model and have attended the first TDR session or participated in the first episode of engagement (where 3 months has elapsed since the date of referral).</p> <ul style="list-style-type: none"> <li>• ≥80% - <b>“Target”</b></li> <li>• Between 70% - 79.9% - <b>“Mid Threshold”</b></li> <li>• &lt;70% - <b>“Lower Threshold”</b></li> </ul>	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>

<b>KPI 4 Component: Efficacy</b>	<p>KPI 4a: The percentage of Service Users on the Face-to-Face Delivery Model for whom:</p> <ul style="list-style-type: none"> <li>• sufficient time has elapsed to have been on the programme for 3 months, who have lost 10% of their baseline weight by the time the Service User passes the 3-month mark on the programme.</li> <li>• ≥55% have lost 10% of weight compared with the baseline weight recorded- <b>“Target”</b></li> <li>• Between 50% - 54.9% have lost 10% of weight compared with the baseline weight recorded - <b>“Mid Threshold”</b></li> <li>• &lt;49.9% have lost 10% of weight compared with the baseline weight recorded- <b>“Lower Threshold”</b></li> </ul>	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	Quarterly
	<p>KPI 4b: The percentage of Service Users on the Digital Delivery Model for whom:</p> <ul style="list-style-type: none"> <li>• sufficient time has elapsed to have been on the programme for 3 months, who have lost 10% of their baseline weight by the time the Service User passes the 3-month mark on the programme.</li> <li>• ≥55% have lost 10% of weight compared with the baseline weight recorded- <b>“Target”</b></li> <li>• Between 50% - 54.9% have lost 10% of weight compared with the baseline weight recorded - <b>“Mid Threshold”</b></li> <li>• &lt;49.9% have lost 10% of weight compared with the baseline weight recorded- <b>“Lower Threshold”</b></li> </ul>	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	Quarterly

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	<p>KPI 4c: The percentage of Service Users on the Face-to-Face Delivery Model for whom:</p> <ul style="list-style-type: none"> <li>• sufficient time has elapsed to have been on the programme for 12 months,</li> </ul> <p>who have lost 10% of their baseline weight by the time the Service User passes the 12-month mark on the programme.</p> <ul style="list-style-type: none"> <li>• <math>\geq 45\%</math> have lost 10% of weight compared with the baseline weight recorded- <b>“Target”</b></li> <li>• Between 40% - 44.9% have lost 10% of weight compared with the baseline weight recorded - <b>“Mid Threshold”</b></li> <li>• <math>&lt; 39.9\%</math> have lost 10% of weight compared with the baseline weight recorded- <b>“Lower Threshold”</b></li> </ul>	<p>As set out in Part 2 of this Schedule 4 (<i>Local Quality Requirements</i>)</p>	Quarterly
	<p>KPI 4d: The percentage of Service Users on the Digital Delivery Model for whom:</p> <ul style="list-style-type: none"> <li>• sufficient time has elapsed to have been on the programme for 12 months,</li> </ul> <p>who have lost 10% of their baseline weight by the time the Service User passes the 12 month mark on the programme.</p> <ul style="list-style-type: none"> <li>• <math>\geq 45\%</math> have lost 10% of weight compared with the baseline weight recorded- <b>“Target”</b></li> <li>• Between 40% - 44.9% have lost 10% of weight compared with the baseline weight recorded - <b>“Mid Threshold”</b></li> <li>• <math>&lt; 39.9\%</math> have lost 10% of weight compared with the baseline weight recorded- <b>“Lower Threshold”</b></li> </ul>	<p>As set out in Part 2 of this Schedule 4 (<i>Local Quality Requirements</i>)</p>	Quarterly

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<p><b>KPI 5 Component: Milestone 2 Retention</b></p>	<p>KPI 5a: For Service Users:</p> <ul style="list-style-type: none"> <li>• who have fulfilled the Face-to-Face Achievement Criteria that relate to Milestone 1; and</li> <li>• for whom sufficient time has elapsed for the Face-to-Face Achievement Criteria that relate to Milestone 2 to have been fulfilled,</li> </ul> <p>to have fulfilled the Face-to-Face Achievement Criteria that relate to Milestone 2.</p> <ul style="list-style-type: none"> <li>• <math>\geq 90\%</math> - <b>“Target”</b></li> <li>• Between 80% - 89.9% - <b>“Mid Threshold”</b></li> <li>• <math>&lt; 80\%</math> - <b>“Lower Threshold”</b></li> </ul>	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>
	<p>KPI 5b: For Service Users:</p> <ul style="list-style-type: none"> <li>• who have fulfilled the Digital Achievement Criteria that relate to Milestone 1; and</li> <li>• for whom sufficient time has elapsed for the Digital Achievement Criteria that relate to Milestone 2 to have been fulfilled,</li> </ul> <p>to have fulfilled the Digital Achievement Criteria that relate to Milestone 2.</p> <ul style="list-style-type: none"> <li>• <math>\geq 90\%</math> - <b>“Target”</b></li> <li>• Between 80% - 89.9% - <b>“Mid Threshold”</b></li> <li>• <math>&lt; 80\%</math> - <b>“Lower Threshold”</b></li> </ul>	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>

<b>KPI 6 Component: Milestone 3 Retention</b>	<p>KPI 6a: For Service Users:</p> <ul style="list-style-type: none"> <li>• who have fulfilled the Face-to-Face Achievement Criteria that relate to Milestone 1; and</li> <li>• for whom sufficient time has elapsed for the Face-to-Face Achievement Criteria that relate to Milestone 3 to have been fulfilled,</li> </ul> <p>to have fulfilled the Face-to-Face Achievement Criteria that relate to Milestone 3.</p> <ul style="list-style-type: none"> <li>• ≥60% - <b>“Target”</b></li> <li>• Between 50% - 59.9% - <b>“Mid Threshold”</b></li> <li>• &lt;50% - <b>“Lower Threshold”</b></li> </ul>	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>
	<p>KPI 6b: For Service Users:</p> <ul style="list-style-type: none"> <li>• who have fulfilled the Digital Achievement Criteria that relate to Milestone 1; and</li> <li>• for whom sufficient time has elapsed for the Digital Achievement Criteria that relate to Milestone 3 to have been fulfilled,</li> </ul> <p>to have fulfilled the Digital Achievement Criteria that relate to Milestone 3.</p> <ul style="list-style-type: none"> <li>• ≥60% - <b>“Target”</b></li> <li>• Between 50% - 59.9% - <b>“Mid Threshold”</b></li> <li>• &lt;50% - <b>“Lower Threshold”</b></li> </ul>	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>

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<b>KPI 7</b>	<b>Component:</b>	KPI 7a: Eligible referrals have a valid data entry, and are not recorded as “not stated” (i.e. [999]) for the following fields: <ul style="list-style-type: none"> <li>Sex</li> <li>Ethnicity</li> <li>95% - <b>“Target”</b></li> </ul>	As set out in Part 2 of this Schedule 4 (Local Quality Requirements)	Monthly
		KPI 7b: Eligible referrals have a valid data entry i.e. an actual weight or height and not a “not stated” or “unknown” entry for the following fields: <ul style="list-style-type: none"> <li>Height</li> <li>Weight</li> <li>Blood Glucose</li> <li>Blood Pressure (where applicable)</li> <li>100% - <b>“Target”</b></li> </ul>	As set out in Part 2 of this Schedule 4 (Local Quality Requirements)	Monthly
<b>KPI 8</b>	<b>Component:</b>	KPI 8: That notification of discharge is communicated to the Service User’s GP and the Service User within 10 Operational Days once the discharge criteria has been met. <ul style="list-style-type: none"> <li>100% - <b>“Target”</b></li> <li>Between 95% - 99.9% - <b>“Mid Threshold”</b></li> <li>&lt;95% - <b>“Lower Threshold”</b></li> </ul>	As set out in Part 2 of this Schedule 4 (Local Quality Requirements)	Monthly

<p><b>KPI 9: Equality of access commencing the programme</b></p>	<p>KPI 9a: For individuals from Black, Asian and other ethnic groups referred to the Face-to-Face Delivery Model the uptake proportions (Milestone 1) are in line with the proportions commencing the service regardless of ethnicity:</p> <ul style="list-style-type: none"> <li>• 100% - <b>“Target”</b></li> <li>• Between 95% - 99.9% - <b>“Mid Threshold”</b></li> <li>• &lt;95% - <b>“Lower Threshold”</b></li> </ul> <p>KPI 9b: For individuals from Black, Asian and other ethnic groups referred to the Digital Delivery Model the uptake proportions (Milestone 1) are in line with the proportions commencing the service regardless of ethnicity:</p> <ul style="list-style-type: none"> <li>• 100% - <b>“Target”</b></li> <li>• Between 95% - 99.9% - <b>“Mid Threshold”</b></li> <li>• &lt;95% - <b>“Lower Threshold”</b></li> </ul>	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>
	<p>KPI 9c: For individuals from the most deprived quintile referred to the Face-to-Face Delivery Model the uptake proportions (Milestone 1) are in line with the proportions commencing the service regardless of deprivation:</p> <ul style="list-style-type: none"> <li>• 100% - <b>“Target”</b></li> <li>• Between 95% - 99.9% - <b>“Mid Threshold”</b></li> <li>• &lt;95% - <b>“Lower Threshold”</b></li> </ul> <p>KPI 9d: For individuals from the most deprived quintile referred to the Digital Delivery Model the uptake proportions (Milestone 1) are in line with the proportions commencing the service regardless of deprivation:</p> <ul style="list-style-type: none"> <li>• 100% - <b>“Target”</b></li> <li>• Between 95% - 99.9% - <b>“Mid Threshold”</b></li> <li>• &lt;95% - <b>“Lower Threshold”</b></li> </ul>	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>



<b>KPI 10: Equality of retention on the TDR phase</b>	<p>KPI 10a: For individuals from Black, Asian and other ethnic groups referred to the Face-to-Face Delivery Model the retention proportions at Milestone 2 are in line with the proportions retained to Milestone 2 regardless of ethnicity:</p> <ul style="list-style-type: none"> <li>• 100% - <b>“Target”</b></li> <li>• Between 95% - 99.9% - <b>“Mid Threshold”</b></li> <li>• &lt;95% - <b>“Lower Threshold”</b></li> </ul> <p>KPI 10b: For individuals from Black, Asian and other ethnic groups referred to the Digital Delivery Model the retention proportions at Milestone 2 are in line with the proportions retained to Milestone 2 regardless of ethnicity:</p> <ul style="list-style-type: none"> <li>• 100% - <b>“Target”</b></li> <li>• Between 95% - 99.9% - <b>“Mid Threshold”</b></li> <li>• &lt;95% - <b>“Lower Threshold”</b></li> </ul>	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>
	<p>KPI 10c: For individuals from the most deprived quintile referred to the Face-to-Face Delivery Model the retention proportions at Milestone 2 are in line with the proportions retained to Milestone 2 regardless of deprivation:</p> <ul style="list-style-type: none"> <li>• 100% - <b>“Target”</b></li> <li>• Between 95% - 99.9% - <b>“Mid Threshold”</b></li> <li>• &lt;95% - <b>“Lower Threshold”</b></li> </ul> <p>KPI 10d: For individuals from the most deprived quintile referred to the Digital Delivery Model the retention proportions at Milestone 2 are in line with the proportions retained to Milestone 2 regardless of deprivation:</p> <ul style="list-style-type: none"> <li>• 100% - <b>“Target”</b></li> <li>• Between 95% - 99.9% - <b>“Mid Threshold”</b></li> <li>• &lt;95% - <b>“Lower Threshold”</b></li> </ul>	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>

<p><b>KPI 11: Equality of retention to end of programme</b></p>	<p>KPI 11a: For individuals from Black, Asian and other ethnic groups referred to the Face-to-Face Delivery Model the retention proportions at Milestone 3 are in line with the proportions retained to Milestone 3 regardless of ethnicity:</p> <ul style="list-style-type: none"> <li>• 100% - <b>“Target”</b></li> <li>• Between 95% - 99.9% - <b>“Mid Threshold”</b></li> <li>• &lt;95% - <b>“Lower Threshold”</b></li> </ul> <p>KPI 11b: For individuals from Black, Asian and other ethnic groups referred to the Digital Delivery Model the retention proportions at Milestone 3 are in line with the proportions retained to Milestone 3 regardless of ethnicity:</p> <ul style="list-style-type: none"> <li>• 100% - <b>“Target”</b></li> <li>• Between 95% - 99.9% - <b>“Mid Threshold”</b></li> <li>• &lt;95% - <b>“Lower Threshold”</b></li> </ul>	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>
	<p>KPI 11c: For individuals from the most deprived quintile referred to the Face-to-Face Delivery Model the retention proportions at Milestone 3 are in line with the proportions retained to Milestone 3 regardless of deprivation:</p> <ul style="list-style-type: none"> <li>• 100% - <b>“Target”</b></li> <li>• Between 95% - 99.9% - <b>“Mid Threshold”</b></li> <li>• &lt;95% - <b>“Lower Threshold”</b></li> </ul> <p>KPI 11d: For individuals from the most deprived quintile referred to the Digital Delivery Model the retention proportions at Milestone 3 are in line with the proportions retained to Milestone 3 regardless of deprivation:</p> <ul style="list-style-type: none"> <li>• 100% - <b>“Target”</b></li> <li>• Between 95% - 99.9% - <b>“Mid Threshold”</b></li> <li>• &lt;95% - <b>“Lower Threshold”</b></li> </ul>	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>

## **Part 2**

1. In Part 2 of this Schedule 4 (*Local Quality Requirements*) the following definitions are used:

<b>“KPIs”</b>	means the KPIs set out in the table in Part 1 of this Schedule 4 ( <i>Local Quality Requirements</i> ), which are also known as the Local Quality Requirements;
<b>“KPI Periods”</b>	means the periods within which the Provider’s performance against each KPI is to be measured, as set out in the column headed “Period over which the Requirement is to be achieved” in the table in Part 1 of this Schedule 4 ( <i>Local Quality Requirements</i> );
<b>“Lower Threshold”</b>	means the Lower Threshold applicable to a KPI, as set out in Part 1 of this Schedule 4 ( <i>Local Quality Requirements</i> ) and, to avoid doubt, is considered a threshold for the purpose of Service Condition 3.1.2;
<b>“Mid Threshold”</b>	means the Mid Threshold applicable to a KPI, as set out in Part 1 of this Schedule 4 ( <i>Local Quality Requirements</i> ) and, to avoid doubt, is considered a threshold for the purpose of Service Condition 3.1.2;
<b>“Target”</b>	means the Target applicable to each of the KPIs, as set out in Part 1 of this Schedule 4 ( <i>Local Quality Requirements</i> ) and, to avoid doubt, the Targets are considered thresholds for the purpose of Service Condition 3.1.2; and
2. If the Provider fails to meet or exceed the Lower Threshold applicable to any of the KPIs for the relevant KPI Period, the Commissioner reserves the right, by notice to the Provider to require that the Provider submits, within 10 Operational Days of the notice, a remedial action plan to the Commissioner that sets out the actions that the Provider will take prior to the end of the next KPI Period applicable to the relevant KPI to remedy the failure to meet or exceed the target in relation to that KPI.
3. If the Provider exceeds the Lower Threshold applicable to any of the KPIs but fails to meet or exceed the Target applicable to that KPI for the relevant KPI Period, the Commissioner reserves the right, by notice to the Provider:
  - 3.1. to issue a Contract Performance Notice to the Provider in accordance with GC 9.4 (Contract Management); or
  - 3.2. to require that the Provider submits, within 10 Operational Days of the notice, a remedial action plan to the Commissioner that sets out the actions that the Provider will take prior to the end of the next KPI Period applicable to the relevant KPI to remedy the failure to meet or exceed the Target in relation to that KPI.

4. Where the Provider does not provide a remedial action plan to the Commissioner within the relevant timescale in accordance with paragraphs 2 and/or 3.2 of Part 2 of this Schedule 4 (*Local Quality Requirements*), the Commissioner may, by notice to the Provider, immediately and permanently retain up to 1% of the Actual Monthly Value applicable to the relevant KPI Period, where the relevant KPI Period is monthly, or up to 1% of the Actual Quarterly Value applicable to the relevant KPI Period, where the relevant KPI Period is Quarterly.
5. Where the Provider has provided a remedial action plan to the Commissioner within the relevant timescale in accordance with paragraphs 2 and 3.2 of Part 2 of this Schedule 4 (*Local Quality Requirements*), then if the Provider:
  - 5.1. fails to meet or exceed the Target applicable to that KPI for the next KPI Period applicable to that KPI, the Commissioner may, by notice to the Provider, immediately and permanently retain up to 1% of the Actual Monthly Value applicable to the relevant KPI Period, where the relevant KPI Period is monthly, or up to 1% of the Actual Quarterly Value applicable to the relevant KPI Period, where the relevant KPI Period is Quarterly, and issue a Contract Performance Notice to the Provider; or
  - 5.2. meets or exceeds the Target applicable to that KPI for the next KPI Period applicable to that KPI, the Commissioner will confirm that the remedial action plan has been achieved.
6. For the avoidance of doubt, nothing in paragraphs 4 or 5 of Part 2 of this Schedule 4 (*Local Quality Requirements*) will prevent the Commissioner from retaining any further sums in relation to the next (or any subsequent) KPI Period for the relevant KPI in accordance with paragraphs 2 or 3 of Part 2 of this Schedule 4 (*Local Quality Requirements*), subject to paragraph 7 of Part 2 of this Schedule 4 (*Local Quality Requirements*).
7. The Commissioner will not retain more than 10% of the Actual Monthly Value applicable to any individual month pursuant to Part 2 of this Schedule 4 (*Local Quality Requirements*).
8. Without prejudice to any other rights or remedies that may be available to the Commissioner under Part 2 of this Schedule 4 (*Local Quality Requirements*), if for any KPI Period the Provider fails to meet or exceed any Target in relation to any KPI that does not have a Mid Threshold figure and a Lower Threshold figure), the Commissioner will be entitled to issue a Contract Performance Notice to the Provider in accordance with GC9.4 (*Contract Management*).
9. The parties acknowledge and agree that for the purposes of GC17.10.4 the Provider will be deemed to be in persistent or repetitive breach of the Quality Requirements if, in the Commissioner's reasonable opinion, the Provider has repeatedly failed to meet or exceed the Targets applicable to any of the KPIs in such a manner as to reasonably justify the Commissioner's opinion that the Provider's conduct is inconsistent with it having the intention or ability to meet or exceed the relevant requirements over a reasonable period of the remaining Contract Term.

## **SCHEDULE 5 – GOVERNANCE**

### **A. Documents Relied On**

**Not applicable**

## SCHEDULE 5 - GOVERNANCE

### B. Provider's Material Sub-Contracts

Sub-Contractor [Name] [Registered Office] [Company number]	Service Description	Start date/expiry date	Processing Personal Data – Yes/No	If the Sub-Contractor is processing Personal Data, state whether the Sub- Contractor is a Data Processor OR a Data Controller OR a joint Data Controller
[DN: To be populated prior to Contract award as appropriate]				

## **SCHEDULE 5 - GOVERNANCE**

### **C. Commissioner Roles and Responsibilities**

**Not Applicable**

## SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

### A. Reporting Requirements

	Reporting Period	Format of Report	Timing and Method for delivery of Report	Service category
<b>National Requirements Reported Centrally</b>				
1. As specified in the Schedule of Approved Collections published at <a href="https://digital.nhs.uk/isce/publication/nhs-standard-contract-approved-collections">https://digital.nhs.uk/isce/publication/nhs-standard-contract-approved-collections</a> where mandated for and as applicable to the Provider and the Services	As set out in relevant Guidance	As set out in relevant Guidance	As set out in relevant Guidance	<b>All</b>
1a. Without prejudice to 1 above, daily submissions of timely Emergency Care Data Sets, in accordance with DAPB0092-2062 and with detailed requirements published at <a href="https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/emergency-care-data-set-ecds/ecds-latest-update">https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/emergency-care-data-set-ecds/ecds-latest-update</a>	As set out in relevant Guidance	As set out in relevant Guidance	Daily	<b>A+E, U</b>
2. Patient Reported Outcome Measures (PROMS) <a href="https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/patient-reported-outcome-measures-proms">https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/patient-reported-outcome-measures-proms</a>	As set out in relevant Guidance	As set out in relevant Guidance	As set out in relevant Guidance	<b>All</b>
<b>National Requirements Reported Locally</b>				
1a. Activity and Finance Report	Monthly	In the format specified in the relevant Information Standards Notice (DCB2050)	[For local agreement]	<b>A, MH</b>
1b. Activity and Finance Report	Monthly	[For local agreement]	[For local agreement]	<b>All except A, MH</b>
2. Service Quality Performance Report, detailing performance against National Quality Requirements, Local Quality Requirements and the duty of candour, including, without limitation: <ul style="list-style-type: none"> <li>a. details of any thresholds that have been breached and breaches in respect of the duty of candour that have occurred;</li> <li>b. details of all requirements satisfied;</li> </ul>	Monthly	[For local agreement]	Within 15 Operational Days of the end of the month to which it relates	<b>All</b>  <b>All</b>



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	Reporting Period	Format of Report	Timing and Method for delivery of Report	Service category
c. details of, and reasons for, any failure to meet requirements				All
3. Where CQUIN applies, CQUIN Performance Report and details of progress towards satisfying any CQUIN Indicators, including details of all CQUIN Indicators satisfied or not satisfied	[For local agreement]	[For local agreement]	[For local agreement]	All
4. Complaints monitoring report, setting out numbers of complaints received and including analysis of key themes in content of complaints	[For local agreement]	[For local agreement]	[For local agreement]	All
5. Report against performance of Service Development and Improvement Plan (SDIP)	In accordance with relevant SDIP	In accordance with relevant SDIP	In accordance with relevant SDIP	All
6. Summary report setting out relevant information on Patient Safety Incidents and the progress of and outcomes from Patient Safety Investigations, as agreed with the Co-ordinating Commissioner	Monthly	[For local agreement]	[For local agreement]	All
7. Data Quality Improvement Plan: report of progress against milestones	In accordance with relevant DQIP	In accordance with relevant DQIP	In accordance with relevant DQIP	All
8. Report on outcome of reviews and evaluations in relation to Staff numbers and skill mix in accordance with GC5.2 (Staff)	Annually (or more frequently if and as required by the Co-ordinating Commissioner from time to time)	[For local agreement]	[For local agreement]	All
9. Report on its performance against the National Workforce Race Equality Standard and action plan setting out the steps the Provider will take to improve performance	Annually	[For local agreement]	By 31 October in each Contract Year; submission to Co-ordinating Commissioner	All
10. (If the Provider is an NHS Trust or an NHS Foundation Trust) report on its performance against the National Workforce Disability Equality Standard and action plan setting out the steps the Provider will take to improve performance	Annually	[For local agreement]	By 31 October in each Contract Year; submission to Co-ordinating Commissioner	All
11. Where the Services include Specialised Services and/or other services directly commissioned by NHS England (or commissioned by an ICB, where NHS England has delegated the function of commissioning those services), specific reports as set out at <a href="https://www.england.nhs.uk/nhs-standard-contract/dc-reporting/">https://www.england.nhs.uk/nhs-standard-contract/dc-reporting/</a>	As set out at <a href="https://www.england.nhs.uk/nhs-standard-contract/dc-reporting/">https://www.england.nhs.uk/nhs-standard-contract/dc-reporting/</a>	As set out at <a href="https://www.england.nhs.uk/nhs-standard-contract/dc-reporting/">https://www.england.nhs.uk/nhs-standard-contract/dc-reporting/</a>	As set out at <a href="https://www.england.nhs.uk/nhs-standard-contract/dc-reporting/">https://www.england.nhs.uk/nhs-standard-contract/dc-reporting/</a>	All

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	Reporting Period	Format of Report	Timing and Method for delivery of Report	Service category
<a href="#">contract/dc-reporting/</a> (where not otherwise required to be submitted as a national requirement reported centrally or locally)				
12. Report on progress against Green Plan in accordance with SC18.2 (NHS Trust/FT only)	Annually	[For local agreement]	[For local agreement]	All
<b>Local Requirements Reported Locally</b>				
13. Data Output Specification	Data to be collected on an ongoing basis in line with the timing set out in the "Data Format Specification" document in Annex 3 of this Schedule 6A.	<p>The format of the report is as set out in the "Data Output Specifications" document in Annex 2 of this Schedule 6A.</p> <p>The data must be inputted into the report format above in accordance with the codes set out in the "Data Format Specification" document in Annex 3 of this Schedule 6A.</p>	To be submitted electronically to the Contract management provider as appointed and advised by the Commissioner using the templates provided within 10 Operational Days of the end of the month to which it relates.	
14. Waiting Times Report	Monthly	<p>Reporting template as provided by the Commissioner or the Commissioner Representative – this will include as a minimum:</p> <ul style="list-style-type: none"> <li>Numbers waiting for course starts (by month of receipt of referral)</li> <li>Reasons for wait</li> </ul>	To be submitted electronically to the Contract management provider as appointed and advised by the Commissioner using the templates provided within 10 Operational Days of the end of the month to which it relates.	

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	Reporting Period	Format of Report	Timing and Method for delivery of Report	Service category
		and and/or non-attendance to date		
15. Capacity Planning Report	Monthly	<p>Reporting template as provided by the Commissioner or the Commissioner Representative – this will include as a minimum:</p> <ul style="list-style-type: none"> <li>• Expected referrals per month</li> <li>• Number of Service Users waiting for course starts</li> <li>• Planned number of courses</li> </ul>	To be submitted electronically to the Contract management provider as appointed and advised by the Commissioner using the templates provided within 10 Operational Days of the end of the month to which it relates.	
16. Service User Surveys Report	Quarterly	Reporting template as provided by Commissioner or the Commissioner Representative	To be submitted electronically to the Contract management provider as appointed and advised by the Commissioner using the templates provided in advance of the Quarterly Review meeting and within 10 Operational Days of the beginning of the month in which that review meeting falls	
17. Operational & Service Delivery Reports – for local contract areas	Monthly	Reporting template as provided by the Commissioner Representative – this will include, as a minimum:	To be submitted electronically to the lead local health economy representative as detailed in a notification by the Commissioner to	

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	Reporting Period	Format of Report	Timing and Method for delivery of Report	Service category
		<ul style="list-style-type: none"> <li>• Number of referrals received (accepted &amp; rejected)</li> <li>• Number of attendees at first session (group face to face only)Number of courses course starts_booked in next 3 months</li> <li>• Number of individuals declining the Service</li> <li>• Waiting times for course starts</li> </ul>	the Provider	

## SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

### A Reporting Requirements

#### Annex 1 – Service Quality Performance Report

The Parties acknowledge that the headings and tables below are the tab headings and the tables set out in the Service Quality Performance Report spreadsheet provided to the Provider.

#### Submission details

Service Quality Performance Report			
Submitted by (name, title & organisation):		Signed off by (name, title & organisation):	
Submitted by (e-mail address):		Signed off by (email address):	
Full Name of Organisation responsible for Submission:		Date Submitted:	

**Duty of Candour Report**

<b>Duty of Candour Report</b>	
This section must be reported:	Monthly
Period covered by report:	Jan-00
Have any breaches of the National Quality Requirement relating to the Duty of Candour occurred?	
If relevant, provide details of the breach:	
If relevant, provide details of and reasons for any failure to meet the requirement in relation to the Duty of Candour:	
If relevant, provide details of consequence actions taken/required:	

**Never Events Report**

<b>Never Events Report</b>	
This section must be reported:	Monthly
Period covered by report:	Jan-00
Have any Never Events occurred?	
If relevant, provide details of action taken consequent to the Never Event and complain with the Never Event Policy framework:	
If relevant, provide details of the Never Event:	
If relevant, provide details and reasons for any failure to meet the requirement in relation to Never Events:	

**Adverse Events Report**

<b>Adverse Events Report</b>	
This section must be reported:	Monthly
Period covered by report:	Jan-00
How many Adverse Events have occurred?	0
For each Adverse Event provide a summary of the adverse event and details of actions taken consequent to the incident:	

**Complaints Report**

<b>Complaints Report</b>	
This section must be reported:	Monthly
Period covered by report:	Jan-00
How many complaints have been received?	
For each complaint, provide a summary of the complaint and details of actions taken consequent to the complaint:	
Provide an analysis of key themes from the complaints:	



## Incidents Report

<b>Incidents Report</b>	
This section must be reported:	Monthly
Period covered by report:	Jan-00
How many incidents requiring reporting have occurred?	0
For each Incident provide a summary of the incident and details of actions taken consequent to the incident:	

## National Workforce Race Equality Standard Report

<b>National Workforce Race Equality Standard Report</b>	
This section must be reported:	Annually
Period covered by report:	Jan-00
Provide details of compliance with the National Workforce Race Equality Standard:	

## Equality and Health Inequality Impact Assessment

Equality & Health Inequality Impact Assessment	
This section must be reported:	annually
Period covered by report:	
Provide details of Equality & Health Inequality Impact Assessment:	

## Equality and Inequality Impact Assessment Action Plan

[illegible]

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Area	Actions	Timescales	Link to Equality Objectives	Associated Monitoring	Update
Leadership and Strategy					
Access and Inclusion (for those with protected characteristics)					
Service Delivery					
Recruitment and Workforce Diversity					

## TDR Product and Equipment Suppliers

TDR Product and Equipment Suppliers							
This section must be reported:	Annually						
Period covered by report:							
Provide details of Total Diet Replacement product and equipment suppliers							

## SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

## A Reporting Requirements

## Annex 2 – Data Output Specification

**The Parties acknowledge that the headings and tables below are the tab headings and the tables set out in the Data Output Specification spreadsheet provided to the Provider.**

## Referrals

[illegible][illegible][illegible]

[illegible][illegible]

[illegible][illegible]

Unique Field ID	H17 Field name	H18 Organisation_code_of_CD_provider	H137 Date_of_session_or_engagement	H119 Type_of_Health_Incident	H120 Date_of_the_health_incident	H121 Type_of_side_effect	H138 Type_of_side_effect_of_her	H126 Type_of_adverse_event	H139 Type_of_adverse_event_other	H127 Fibre_Supplement_pack_provided	H128 Date_fibre_Supplement_pack_provided	H130 Has_the_capillary_blood_glucose_flag_been_triggered	H131 Date_capillary_blood_glucose_flag_triggered	H132 Has_blood_pressure_flag_been_triggered	H133 Date_blood_pressure_flag_triggered	H124 Serious_adverse_event_NLU	H125 Date_serious_adverse_event_occurred_NLU	H122 Programme_deintensified	H123 Date_programme_deintensified	H146 Date_programme_reintnsified	H129 Any_alerts_discussed_with_MedicalDirector	H134 Number_of_unique_alert_s_given_to_primary_car	H135 Date_of_alert_given_to_primary_care	H136 Action(s)_taken
Format	AN12	AN8	YYYY-MM-DD	AN2	YYYY-MM-DD	AN2	FreeText (AlphaNumericSpecial 50)	AN2	FreeText (AlphaNumericSpecial 200)	AN2	YYYY-MM-DD	AN2	YYYY-MM-DD	AN2	YYYY-MM-DD	AN2	YYYY-MM-DD	AN2	YYYY-MM-DD	AN2	numeric	YYYY-MM-DD	FreeText (AlphaNumericSpecial 200)	
Allow NULLS?	N	N	N	N		Y	Y	Y	Y	Y	Y	Y	Y	Y	Y			Y	Y	Y	Y	Y	Y	



## SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

### A Reporting Requirements

#### Annex 3 – Data Format Specification

The Parties acknowledge that the headings and wording/tables below are the tab headings and the wording/tables set out in the Data Format Specification spreadsheet provided to the Provider.

#### Low Calorie Diet Minimum Data Set Guidance

##### Low Calorie Diet Minimum Data Set Guidance

- The minimum data set for the Low Calorie Diet pilot programme consists of 3 files; Referrals, Contacts and Health Incidents
- A separate Finance file is also required for invoicing purposes
- **Referrals** contains all the participant and pathway data. Records are updated throughout the pathway, up to discharge
- **Contacts** contains 1 row for every planned session or engagement in line with the minimum episodes of engagement as defined in the spec. For example, a SU that completes the programme without a rescue package will have a minimum of 20 rows (regardless of delivery method) by the end of the programme
- If a providers planned standard pathway includes more than the minimum number of sessions as set out in the spec, these should all be submitted in the minimum data set. Please provide standard pathway details to the email address below
- For SU's on a face to face delivery method, anything outside the delivery of sessions (or catch up sessions) should not be submitted including follow up calls or digital engagements
- If a participant takes part in a rescue package, additional rows should be added to document each weekly session that is booked to take place during the rescue package.
- For digital contracts the number of engagements that take place within the timeframe should be included on the appropriate row. All Digital engagements will fall into a digital session engagement period
- See Digital Engagement Periods tab for **example of digital session engagement periods**
- **Health Incidents** contains details of side effects and adverse events reported by participants
- Submissions include all data from the commencement of the programme to the end of the most recent month. For example in September 2021 data from 1 September 20 to 31 August 21 is submitted
- There are 2 submissions each month; version 1 is due by 5pm on working day 10, version 2 is due by 5pm on working day 20
- Submissions are made via the Digital Landing Portal (DLP). For more information and to get set up on the DLP please visit <https://digital.nhs.uk/services/data-landing-portal>
- The DLP recipient organisation is DSCRO South (South Collaborative)
- **Please send any queries to [scwcsu.lcdpilot@nhs.net](mailto:scwcsu.lcdpilot@nhs.net) and [scwcsu.healthieryou@nhs.net](mailto:scwcsu.healthieryou@nhs.net)**

##### Key

The following colours have been used to highlight changes made to the previous version of the MDS

- Field or entry no longer used. We are unable to delete fields due to historic data so entries to retired fields should be null. Retired entries (codes) should not be used**
- Change to existing field or entry (code) or expansion of existing guidance**
- New field or entry (code)**

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## MDS Referrals

Unique Field	Field name	Format	Codes	Data Values	Time of data	Additional information
	<b>Administrative data</b>					
R001	Date_of_Referral	DATEYYYY-			Point of referral	The date the referral is received by provider
R088	Source_of_Referral	an6 (6 char)	1 2	Referral from GP Transfer		Transfer to be used when transferring from one contract to another, whether within a provider or to a different provider
R002	Unique_Referral_ID	an12 (as example)				Unique Id within provider
R003	Organisation_code_of_referrer	an6 (6 char)				The code of the referring organisation. In most cases this is a NHS organisation code. If the referral is from a private organisation without a national code then providers should develop a unique code for each organisation. For transfers, the organisation code of the transferring provider should be entered here
R004	Registered_practice_code	an6 (6 char)				The code of the participant's GP practice.
R005	Organisation_code_of_LCD_provider	an6				Code allocated to provider of LCD by NHS Digital <a href="https://digital.nhs.uk/services/organisation-data-service">https://digital.nhs.uk/services/organisation-data-service</a>
R006	NHS_Number	nnnnnnnnnn				NHS number is mandatory.
R007	Date_of_referral_HbA1c_reading	DATEYYYY-MM-DD				HbA1c reading provided at referral. All referrals should have a referral HbA1c reading within 12 months prior to referral to the LCD Programme. It is expected that submitted HbA1c reading will be 87 mmol/mol or lower (although obviously not all of these would be considered eligible for the service). Values outside of this range may not be used in analysis.
R008	Referral_HbA1c_reading	int				If there is any concern that HbA1c may have changed since last measured, such that repeat testing may indicate that the individual would not be eligible for the LCD programme at present, HbA1c should be rechecked before referral is considered.
R009	Height	numeric	n.nn	[In metres]		The height of the person in metres. It is expected that most heights submitted will fall within the range 1m - 2.5 m. Values outside of this range may not be used in analysis.
R010	Date_of_referral_weight_measurement	DATEYYYY-MM-DD		DATE		Referral weight must be taken within 12 months prior to referral date to be eligible. Self-measured weight is acceptable for referral. If this cannot be obtained, a clinic-measured value within the last 12 months may be used, provided there is no concern that weight may have reduced since last measured such that the individual would not be eligible for the LCD programme at present.
R011	Referral_weight_measurement	numeric	nnn.nn	[Kilograms]		
R147	On_Hold_Eligibility_Check	an1	Y	Yes		To be used when eligibility information is missing or needs to be checked. Once eligibility information is complete, field can be null
R150	Date_Eligibility_Complete	DATEYYYY-				The date eligibility information is complete
R012	Family_Name	an68				Name, address and email and telephone should only be submitted if the participant agrees to be contacted for evaluation purposes.
R013	Given_Name	an68				
R014	Address_Line_1	an68				5 lines available but only 3 required. However email or telephone can be collected instead of postal address if preferred.
R015	Address_Line_2	an68				
R016	Address_Line_3	an68				
R017	Address_Line_4	an68				
R018	Postcode	an8				Postcode is mandatory for all participants.
			ZZ99	No fixed abode		

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R019	Email	an68			
R020	Telephone	an16			
R021	Date_of_Birth	DATEYYYY-			
R022	Is_Service_User_on_Learning_Disability_Register	an1	Y Yes N No X Not known		The date of birth of the participant. Whether the participant has been recorded on the learning disability register at their general practice. The register is produced by the practice from diagnostic information and therefore participants may not know that they are on the register. This information should only be collected from referrers / General Practices and not from the participant.
R023	Is_Service_User_on_SML_Register	an1	Y Yes N No X Not known		Whether the participant has been recorded on the Serious Mental Illness register at their general practice. The register is produced by the practice from diagnostic information and therefore participants may not know that they are on the register. This information should only be collected from referrers / General Practices and not from the participant.
R024	Sex	an1	1 Male 2 Female 3 Indeterminate Z Not Stated (Person asked but declined to provide a response) X Not known / not recorded		The participants' sex. Indeterminate means "unable to be classified as either male or female" – this may also be known as intersex.
R025	Ethnicity	an2	White A White British or white Mixed British B White Irish C Any other white background Mixed D White and Black Caribbean E White and Black African F White and Asian G Any other mixed background Asian or Asian British H Indian J Pakistani K Bangladeshi L Any other Asian background Black or Black British M Caribbean N African P Any other black background Other Ethnic Groups R Chinese S Any other ethnic group Z Not Stated 99 Not Known		The ethnicity of the participant, as specified by the participant. "Not Stated" should be used where the participant has been given the opportunity to state their ethnic category but chose not to. "Not known" should only be used when the participant has not been asked. This is required to assess eligibility with regards to BMI range.
R026	Date_diagnosed_with_Type_2_Diabetes	DATEYYYY-			Individual must have been diagnosed within the last 6 years prior to referral date to be eligible for programme
R027	Medication_discussed	an1	Y Yes N No X Not known		Participant should have discussed medication changes with their GP, if confirmed mark as "Yes". If no such discussion has taken place, mark as "No" and defer the start date. This is required for the Individual Assessment. Not known should be used as a temporary default entry until relevant information is captured.
R028	Confirmation_of_medication_eligibility	an1	Y Yes N No - participant discharged X Not known		Confirmation that the participant has agreed with the referrer, as part of their medication review, that they will cease taking sulphonylureas / meglitinides / SGLT2 inhibitors prior to commencement of TDR. Not known should be used as a temporary default entry until relevant information is captured.
R029	Taking_diabetes_medication	an1	Y Yes N No X Not known		Whether the participant is taking diabetes medication on referral. This is required to know what the HbA1c eligible range is. Not known should be used as a temporary default entry until relevant information is captured.
R030	Taking_blood_pressure_lowering_meds	an1	Y Yes N No X Not known		Whether the participant is taking blood pressure lowering medication on referral. If so, a blood pressure check must be done regularly whilst on the programme. Not known should be used as a temporary default entry until relevant information is captured.
R089	Referral_Blood_Pressure_Systolic_and_Diastolic	varchar(7)			This is only required for those who are on blood pressure lowering medication.
R090	Date_of_Referral_Blood_Pressure_Measurement	DATEYYYY-			If date has not been provided, entry can be null
R032	Metformin	an1	Y / N		Metformin
R033	Sulphonylureas	an1	Y / N		Gliclazide, Glibenclamide, Glimpeptide Must NOT be taken during TDR phase – risk of hypoglycaemia
R034	Meglitinides	an1	Y / N		Repaglinide, Nateglinide Must NOT be taken during TDR phase – risk of hypoglycaemia
R035	Pioglitazone	an1	Y / N		Pioglitazone
R036	DPP4_inhibitors_(gliptins)	an1	Y / N		Linagliptin, Alogliptin, Sitagliptin, Saxagliptin, Vildagliptin
R037	SGLT2_inhibitors_(flosins)	an1	Y / N		Dapagliflozin, Canagliflozin, Empagliflozin, Ertugliflozin Must NOT be taken during TDR phase – risk of ketoacidosis
R038	GLP1_analogues_(tides)	an1	Y / N		Eisenatide, Dulaglutide, Liraglutide, Lixisenatide, Semaglutide
R039	Acarbose	an1	Y / N		Acarbose
<b>Assessment of Health Inequalities</b>					
R040	Date_of_initial_contact_attempt	DATEYYYY-MM-DD		Before IA and after referral	The date the participant is first contacted to be invited to an Individual Assessment.
R041	Method_of_initial_contact_attempt	int/an1	1 Letter 2 Telephone 3 Text 4 E-mail 5 In person		The communication method by which a participant is contacted to attend an Individual Assessment.
R042	Date_of_initial_contact_attempt_2	DATEYYYY-			In the event of no response, make an attempt to contact the participant at least another 2 times, using at least 2 different methods of contact.
R043	Method_of_contact_attempt_2Method_of_contact_attempt_2	int/an1	1 Letter 2 Telephone 3 Text 4 E-mail		The communication method by which a participant is contacted to attend an Individual Assessment.

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			5	In person	
R044	Date_of_initial_contact_attempt_3	DATEYYYY-			In the event of no response, make an attempt to contact the participant at least another 2 times, using at least 2 different methods of contact.
R045	Method_of_contact_attempt_3	int/an1	1	Letter	This is the communication method by which a participant is contacted to attend an Individual Assessment.
			2	Telephone	
			3	Text	
			4	E-mail	
			5	In person	
R046	Date_of_Acceptance_to_take_part_in_programme	DATEYYYY-MM-DD			Once a person has agreed to participate in the programme this should be populated with the date that they accept. If person does not accept, has yet to accept or is never able to be contacted this will remain blank, and if appropriate the participant should be discharged with a date of discharge and reason for discharge completed. If the person declines the IA this should remain blank and the reason for decline
R047	Reason_for_declining	int/an1	1	No reason given	The reason given by the person for declining to attend an Individual Assessment. Please refer to the Service Specification and any other guidelines from NHS England regarding the eligibility criteria. Date of acceptance should remain blank if a person declined the service. If a participant withdraws after this stage the decline reason should remain blank and the most appropriate discharge reason used (see below for further details)
			2	Unable to commit time	
			3	Inconvenient time	
			4	Inconvenient location	
			5	Not motivated at this time	
			6	Other	
R048	Religion	an1	A	Bahai's	A participant's religious or other belief system affiliation. Where the participant has been asked but they are unsure "Other" should be used. "Not known" should only be used when the participant has not been asked. Religion is a protected characteristic so is collected for equality and monitoring equity of access purposes.
			B	Buddhist	
			C	Christian	
			D	Hindu	
			E	Jain	
			F	Jewish	
			G	Muslim	
			H	Pagan	
			I	Sikh	
			J	Zoroastrian	
			K	Other	
			L	None	
			M	Declines to Disclose	
			N	Patient Religion Unknown	
R049	Does_the_Service_User_have_a_disability	an1	1	Yes	Whether the participant has a disability. This can be where they have been diagnosed as disabled, or they consider themselves to be disabled.
			2	No	
			3	Not Stated (Person asked but declined to provide a response)	
			4	Not known	
R050	Behaviour_and_Emotional	an1	Y/N	Behaviour and Emotional	The participant's disabilities. This should only be completed if the participant has said "Yes" to "Does the participant have a disability?" Each of these fields must be completed with either a "Y" for "Yes", or a "N" for "No". The participant can say "Yes" to more than one disability.
R051	Hearing	an1	Y/N	Hearing	
R052	Manual_Dexterity	an1	Y/N	Manual Dexterity	
R053	Memory_or_ability_to_concentrate_learn_or_understand_(Learning_Disability)	an1	Y/N	Memory or ability to concentrate, learn or understand (Learning Disability)	
R054	Mobility_and_Gross_Motor	an1	Y/N	Mobility and Gross Motor	
R055	Perception_of_Physical_Danger	an1	Y/N	Perception of Physical Danger	
R056	Personal_SelfCare_and_Continence	an1	Y/N	Personal, Self-Care and Continence	
R057	Progressive_Conditions_and_Physical_Health_(such_as_HIV_cancer_multiple_sclerosis_fits_etc)	an1	Y/N	Progressive Conditions and Physical Health (such as HIV, cancer, multiple sclerosis, fits etc.)	
R058	Sight	an1	Y/N	Sight	
R059	Speech	an1	Y/N	Speech	
R060	Other	an1	Y/N	Other	
R061	Is_Service_User_a_smoker	an1	1	Smoker	Current smoker: Adults who smoke cigarettes nowadays.
			2	Ex-smoker	Ex-smoker: Adults who used to smoke cigarettes regularly but no longer do so.
			3	Non-smoker	<a href="http://content.digital.nhs.uk/catalogue/PUB17526/stat-smok-eng-2015-rep.pdf">http://content.digital.nhs.uk/catalogue/PUB17526/stat-smok-eng-2015-rep.pdf</a>
			2	Not Stated (Person asked but declined to provide a response)	
			X	Not known	
R062	Is_the_Service_User_happy_to_receive_the_service_in_English	an1	Y	Yes	
			N	No	
R063	Preferred_language	int	1	English	What language would the participant have preferred the programme to be delivered in?
			2	Arabic	
			3	Bengali	
			4	British Sign Language	
			5	Chinese	
			6	Farsi	
			7	Gujarati	
			8	Hindi	
			9	Kurdish	
			10	Lithuanian	
			11	Nepali	
			12	Pakistani	
			13	Polish	
			14	Punjabi	
			15	Slovak	
			16	Somali	
			17	Tamil	
			18	Turkish	
			19	Urdu	
			20	Other	

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R064	Preferred_language_Other	freetext (50)			If Preferred Language is Other - 20 then please specify the additional language here. This should only be used where the preferred language is not one of the 19 already listed.
R065	Delivered_language	int	1 English 2 Arabic 3 Bengali 4 British Sign Language 5 Chinese 6 Farsi 7 Gujarati 8 Hindi 9 Kurdish 10 Lithuanian 11 Nepali 12 Pakistani 13 Polish 14 Punjabi 15 Somali 16 Slovak 17 Tamil 18 Turkish 19 Urdu 20 Other		What language was the programme delivered in?
R066	Delivered_language_Other	freetext (50)			If Delivered Language is Other - 20 then please specify the additional language here. This should only be used where the delivered language is not one of the 19 already listed.
R067	Consent_for_future_contact_for_evaluation	an1	Y Yes N No (blank) Not Recorded		The person agrees to be contacted in the future to take part in the evaluation of LCD.
R068	Confirmation_of_eligibility	an1	Y Yes N No		Confirm that the participant remains eligible for LCD TDR. Please refer to the Service Specification and any other guidelines from NHS England regarding the eligibility criteria.
			X Not known		Not known should be used as a temporary default entry until relevant information is captured.
R091	Date_of_Confirmation_of_Eligibility	DATEYYYY-MM-DD			The date the participants eligibility was confirmed. If SU choice means there's a gap between IA and TDR start, the date the SU's eligibility was re-confirmed prior to TDR start should be provided. If multiple dates apply, the latest should be provided.
R069	Date_of_Individual_Assessment_Attendance	DATEYYYY-MM-DD			The date the participant attended/participated in the Individual Assessment. If a planned IA was not attended, enter the actual date of attendance once it has been attended
R092	Delivery_Method_of_Individual_Assessment		1 1:1 in person 2 Remote		The method of delivery for the individual assessment applies to Framework 1 face to face delivery only Not applicable to wave 1 and 2 contracts and should be NULL
R093	Delivery_Method_Choice		1 1:1 in person 2 Digital		The choice of delivery method selected by the participant Not applicable to wave 1 and 2 contracts and should be NULL
R070	SU_agrees_attend_diabetes_review_appts_at_GP_practice_when_remission_is_achieved	an1	Y N		
R071	SU_notify_GP_practice_of_any_unexpected_or_concerning_symptoms_which_are_urgent	an1	Y N		
R072	SU_will_notify_GP_practice_if_they_disengage_or_drop_out_before_the_end_of_the_intervention	an1	Y N		
R073	Service_user_has_no_known_allergies_to_the_ingredients_of_the_issued_TDR_products	an1	Y N		Yes - the participant does not have any known allergies to TDR product ingredients No - the participant does have known allergies to TDR product ingredients
R074	Date_of_Individual_Assessment_booking_attempt_1_following_non-attendance	DATEYYYY-MM-DD		If needing to rebook IA	In the event of non-attendance, make an attempt to re-book at least 3 times, using at least 2 different methods of contact.
R075	Method_of_contact_attempt_1_following_non-attendance	an1int	1 Letter 2 Telephone 3 Text 4 E-mail 5 In person		This is the communication method by which an participant is contacted to re-book the session.
R076	Date_of_Individual_Assessment_booking_attempt_2_following_non-attendance	DATEYYYY-MM-DD			In the event of non-attendance, make an attempt to re-book at least 3 times, using at least 2 different methods of contact.
R077	Method_of_contact_attempt_2_following_non-attendance	an1int	1 Letter		This is the communication method by which an participant is contacted to re-book the session.

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			2	Telephone		
			3	Text		
			4	E-mail		
			5	In person		
R078	Date_of_Individual_Assessment_booking_attempt_3_following_non-attendance	DATEYYYY-MM-DD				In the event of non-attendance, make an attempt to re-book at least 3 times, using at least 2 different methods of contact.
R079	Method_of_contact_attempt_3_following_non-attendance	an1int	1	Letter		This is the communication method by which an participant is contacted to re-book the session.
			2	Telephone		
			3	Text		
			4	E-mail		
			5	In person		
R143	On_Hold_Waiting	an1	Y	Yes		To be used when a participant is waiting for a particular group or delivery method (eg. a particular language or in person to resume). Waiting times as per the service specification apply.
R080	Planned_date_of_commencement_of_TDR	DATEYYYY-MM-DD			Starting the programme	The date that the participant and provider planned for the participant to begin TDR.
R081	Actual_date_of_commencement_of_TDR	DATEYYYY-MM-DD				The date that the participant commenced TDR as confirmed by the provider. It may be the same as the planned date, or different if the SU did not begin on the planned day after all.
R094	Baseline_Weight	numeric	nnn.nn	[Kilograms]		The weight captured at the first session/engagement within the TDR phase. If this doesn't fall on the TDR start date then the weight captured closest to this date (within 7 days either side) should be provided.
R140	Actual_date_of_commencement_of_FR	DATEYYYY-MM-DD			During the	The date that the participant commenced FR as confirmed by the provider
R141	Actual_date_of_commencement_of_WM	DATEYYYY-MM-DD				The date that the participant commenced WM as confirmed by the provider
R142	Rescue_Package_Start_Date	DATEYYYY-MM-DD				If a participant is eligible for a rescue package and accepts the offer, the date the rescue package is started
R143	Rescue_Package_End_Date	DATEYYYY-MM-DD				If a participant is eligible for a rescue package and accepts the offer, the date the rescue package ends. The maximum duration for a rescue package is 28 days.
R095	Pause_Start_Date	DATEYYYY-MM-DD				Please see service specification for further details relating to a pause
R096	Pause_End_Date	DATEYYYY-MM-DD				Please see service specification for further details relating to a pause
R082	Date_of_Digital_Registration	DATEYYYY-MM-DD			Progressing through the Digital	The date that the digital participant registers on the digital platform. This will be blank for one to one and group contracts. This is required for digital MS1 payment.
R083	Date_of_TimeStamped_Log_In_MS2	DATEYYYY-MM-DD				The date at which the participant logs in to the digital platform in the MS2 period. This will be blank for one to one and group contracts. This is required for digital MS2 payment.
R084	Date_of_TimeStamped_Log_In_MS3	DATEYYYY-MM-DD				The date at which the participant logs in to the digital platform in the MS3 period. This will be blank for one to one and group contracts. This is required for digital MS3 payment.
R097	GP_notified_of_referral_receipt	an1	Y	GP notification sent		
R098	Date_GP_notified_of_referral_receipt	DATEYYYY-MM-DD	N	GP notification not sent [Date]		
R099	GP_notified_of_IA_Completion	an1	Y	GP notification sent		
R100	Date_GP_notified_of_IA_Completion	DATEYYYY-MM-DD	N	GP notification not sent [Date]		
R101	GP_notified_of_TDR_Start	an1	Y	GP notification sent		
R102	Date_GP_notified_of_TDR_Start	DATEYYYY-MM-DD	N	GP notification not sent [Date]		
R103	GP_notified_of_TDR_End	an1	Y	GP notification sent		
R104	Date_GP_notified_of_TDR_End	DATEYYYY-MM-DD	N	GP notification not sent [Date]		
R105	GP_notified_of_pause	an1	Y	GP notification sent		
R106	Date_GP_notified_of_pause	DATEYYYY-MM-DD	N	GP notification not sent [Date]		
R107	GP_notified_of_programme_completion	an1	Y	GP notification sent		
R108	Date_GP_notified_of_programme_completion	DATEYYYY-MM-DD	N	GP notification not sent [Date]		
R087	GP_notified_of_discharge	an1	Y	GP notified of completion status and outcomes		
R109	Date_GP_notified_of_discharge	DATEYYYY-MM-DD	N	GP not notified of completion status and outcomes [Date]		The date notification of discharge was sent to GP
R085	Date_of_discharge	DATEYYYY-MM-DD			At discharge	The date the participant was discharged
R086	Reason_For_Discharge	intan2	1	Participant completed the programme		A reason for discharge should be selected for anyone discharged, whether they have started the programme or not. Please choose the most appropriate reason from the list. 'Other' should be used as a last resort only when the preceding options are not applicable.
			2	Incomplete - participant taking incompatible medication		1 - finishes the programme (1 year). If final session is missed reason 8 should be used
			3	Incomplete - participant did not respond within 1 month of referral		2 - usually identified before IA but would be known at IA at the latest
			4	Incomplete - participant declined service prior to starting		3 - only applicable before date_of_acceptance
			5	Incomplete - participant accepted IA invitation but has not attended within 2 months of contact		4 - only applicable before IA attended (Reason_for_Decline also required)
			6	Incomplete - participant not eligible on contact		5 - only applicable before IA attended
						6 - usually identified before IA but would be known at IA at the latest. Please provide reason for ineligibility in additional fields provided
			12	Incomplete - missing information meaning eligibility cannot be confirmed		12 - only applicable before IA attended
			13	Incomplete - missing other required information (not eligibility related)		13 - only applicable before IA attended

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			7	Incomplete - participant has not attended first intervention session within 6 months of referral OR after 3 suitable offers		7 - only applicable after IA and before first session has been attended
			8	Incomplete - participant disengaged during programme		8 - only applicable after TDR start date
			14	Incomplete - participant unable to comply		14 - only applicable after TDR start date
			9	Incomplete - participant became pregnant		9 - applicable at any time in the pathway
			10	Incomplete - adverse event		10 - only applicable after TDR start date
			15	Incomplete - participant did not want to continue with chosen delivery method		15 - only applicable to framework 1 and after TDR start date
			16	Incomplete - participant unable to restart following pause		16 - only applicable following a pause, pause start date should also be present (please see service spec for more details on pauses)
			17	Transferred to other provider / contract		17 - to be used when transferring from one contract to another, whether within a provider or to a different provider
			11	Incomplete - other		11 - only to be used as a last resort if any of the above list do not cover the reason, applicable at any time in the pathway
						<b>If a SU is discharged as ineligible (Reason_For_Discharge = 6) please provide reason(s) for ineligibility. More than 1 can be provided for each SU, if applicable. These should only be used where the data has been provided and it confirms the SU is ineligible, not if data is missing meaning eligibility cannot be confirmed.</b>
R110	Ineligible_Age		Y/Null			Age outside permitted range
R111	Ineligible_Date_of_Diagnosis		Y/Null			Date of diagnosis outside permitted range
R112	Ineligible_BMI		Y/Null			BMI outside permitted range
R113	Ineligible_HbA1c		Y/Null			Date or reading outside permitted range
R114	Ineligible_Diabetes_Review_Attendance		Y/Null			Service user has not attended last diabetes review
R115	Ineligible_Insulin		Y/Null			Service user is currently taking insulin
R116	Ineligible_Pregnant_Breastfeeding		Y/Null			Service user is currently pregnant, planning to become pregnant within next 6 months or currently breastfeeding
R117	Ineligible_Comorbidty		Y/Null			Service user has at least 1 of the comorbidities listed in the service specification
R118	Ineligible_Bariatric_Surgery		Y/Null			Service user has had bariatric surgery
R119	Ineligible_Understanding_or_Meet_Demands		Y/Null			Service user is unable to understand or meet the demands of the programme
R120	Ineligible_Medication_Changes_in_Writing		Y/Null			Service user does not have medication changes provided in writing
R121	Ineligible_ReReferral		Y/Null			Service user has previously been referred to the programme and started TDR
R122	Ineligible_Other		Y/Null			Service user is ineligible for a reason not listed above

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## MDS Contacts

All Contracts - Enter 1 row for every planned session or engagement in line with the minimum episodes of engagement as defined in the spec. See Guidance tab for further information						
Unique Field ID	Field name	Format	Code	Data Values	Time of Data Collection	Additional information
C088	Unique_Referral_ID	an12 (as example)			For every core session/engagement	The same unique referral id as used for the participant in the Referral dataset.
C089	Organisation_code_of_LCD_provider	an8				The LCD provider code.
C090	Phase_of_intervention	an35	TDR	TDR		The provider should indicate what stage of the programme the participant is in for every session/engagement.
			FR	Food Reintroduction		Where a participant is in Weight Maintenance but has been given a rescue package at the last session/engagement, the provider should select WMRP to indicate that the participant is using a rescue package.
			WM	Weight Maintenance		If the phase of the programme deviates from the plan, the phase provided should reflect the phase the
			WMRP	Weight Maintenance - Rescue Package		The date of the booked session / the date the digital engagement occurs.
C091	Date_of_Session_or_Engagement	DATE YYYY-MM-DD		[Date]		For digital, the date should be provided of the engagement with a health coach ('Conversation With Health Coach' or 'Exchange of Messages With Health Coach'). If more than 1 has taken place within the engagement period, please provided the latest
C001	Session_or_Engagement_Number	int/an2				Sessions should be numbered 1-20. Sessions that take during a rescue package should have the phase_of_intervention coded as WMRP and the session prefixed with R. Rescue package sessions start at 1 (eg. R1, R2, etc). Where a core sessions/engagement takes place during a rescue package and the weekly rescue package session is incorporated into this, the core session number should take precedence and the phase coded as WMRP. For Digital anything that takes place before engagement period 1 is session 0, anything that takes place after week 54 is session 100.
C092	Attendance	int/an1	1	Attended		For digital, if an engagement with a coach (Conversation with Health Coach or Mentor or Exchange of messages with a health coach or mentor) has not taken place in the digital engagement period, the attendance should be 2 - did not attend
			2	Did not attend		
			3	Cancelled (by provider)		
C093	Facilitator_Qualification	int/an2	11	Nutritionist		The primary qualification (as relevant to the programme) of the facilitator.
			12	Health Professional (Nurse)		For digital engagements, if more than 1 engagement has taken place within the engagement period with different facilitators, please submit the qualification that appears first in the list provided.
			13	Health Professional (Health Trainer)		If a session or engagement was not attended, the facilitator qualification of the planned session should be provided.
			14	Health Professional (Dietician)		Option 10 is no longer a valid entry.
			15	Health Professional (Physiotherapist)		
			16	Health Practitioner (Practitioner Psychologist)		
			17	Physical Activity Professional		



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			18	Other (paid)		
			19	Other (volunteer)		
			10	None (digital engagement) - no longer used		
C094	Type_of_Contact	int/an1	1	In person group		This should be completed for every contact. For wave 1 and wave 2 contracts, this should usually match the delivery method assigned at contract level. Alternative delivery mechanisms may be used to support delivery and participant engagement eg. a planned 1:1 session on group delivery as part of the pathway For framework 1 contracts, this should match the delivery method selected by the SU for that session (or catch up session) (option 2, 5 or 6 for 1:1 or option 7 for digital). In person relates to physical face to face; remote telephone is traditional phone calls; remote web is video calls (teams, zoom etc.) Digital is any interactive content (e.g. watch a video or take a quiz) Length in minutes of session. Only required for face to face delivery (remote group, in person group, remote 1:1, in person 1:1)
			2	In person 121		
			3	Remote (telephone) group		
			4	Remote (web) group		
			5	Remote (telephone) 121		
			6	Remote (Web) 121		
			7	Digital		
C095	Length_of_Contact	int		[In minutes]		
C096	Type_Of_Engagement_NLU	int/an2	1	Conversation with Health Coach or Mentor		No longer used
			2	Participation in an online group Conversation		
			3	Exchange of messages with a health coach or mentor (min message limit applies)		
			4	Accessing education materials via digital platform		
			5	Personalised Goal setting or Action Plan agreed		
			6	Watch a Video or Complete A Quiz		
			7	Use of tracking technology with associated data logged		
			8	Recording of achievement against set goals		
			9	Method A		
			10	Method B		
C002	Engagement_Conversation_With_Health_Coach_Number	int				Only required to be completed for digital participants. Count of all engagements during engagement period
C003	Engagement_Conversation_With_Health_Coach_Length	int		[In minutes]		Only required to be completed for digital participants. Cumulative length of all engagements during engagement period
C004	Engagement_Exchange_of_Messages_With_Health_Coach_Number	int				Only required to be completed for digital participants. Count of all engagements during engagement period. Minimum message limit for exchange of messages with health coach or mentor is 3 each way within 24 hour period.
C005	Engagement_Exchange_of_Messages_With_Health_Coach_Length	int		[In minutes]		Only required to be completed for digital participants. Cumulative length of all engagements during engagement period
C006	Engagement_Participation_In_Online_Group_Number	int				Only required to be completed for digital participants. Count of all engagements during engagement period
C007	Engagement_Participation_In_Online_Group_Length	int		[In minutes]		Only required to be completed for digital participants. Cumulative length of all engagements during engagement period
C008	Engagement_Access_Education_Materials_Number	int				Only required to be completed for digital participants. Count of all engagements during engagement period
C009	Engagement_Access_Education_Materials_Length	int		[In minutes]		Only required to be completed for digital participants. Cumulative length of all engagements during engagement period
C010	Engagement_Goal_Setting_or_Action_Plan_Number	int				Only required to be completed for digital participants. Count of all engagements during engagement period
C011	Engagement_Goal_Setting_or_Action_Plan_Length	int		[In minutes]		Only required to be completed for digital participants. Cumulative length of all engagements during engagement period
C012	Engagement_Video_or_Quiz_Number	int				Only required to be completed for digital participants. Count of all engagements during engagement period
C013	Engagement_Video_or_Quiz_Length	int		[In minutes]		Only required to be completed for digital participants. Cumulative length of all engagements during engagement period
C014	Engagement_Tracking_Technology_Data_Length	int				Only required to be completed for digital participants. Count of all engagements during engagement period
C015	Engagement_Tracking_Technology_Data_Number	int		[In minutes]		Only required to be completed for digital participants. Cumulative length of all engagements during engagement period
C016	Engagement_Goal_Recording_Number	int				Only required to be completed for digital participants. Count of all engagements during engagement period

C017	Engagement_Goal_Recording_Length	int		[In minutes]		Only required to be completed for digital participants. Cumulative length of all engagements during engagement period
C144	TDR_Consumption	an1	1	Full TDR		Captures TDR product consumption Only applicable during TDR, FR and WMRP phases or following a Rescue Package (if required to record wean off products) If more than 1 applies since the last session please select the one that applies for majority of days between the sessions Full TDR - TDR has been consumed as defined in the service specification Partial TDR - anything less than full adherence to the guidance defined in the spec either due to the participant being in the food reintroduction phase or for another reason in the list provided. If selecting option 3, the number of full days TDR has been missed can be entered in the next question (#99) Please see service specification relating to the contract area regarding partial rescue packages
			2	Partial TDR - FR/WMRP		
			3	Partial TDR - participant unable to fully comply		
			4	Partial TDR - adverse event		
			6	No TDR - FR		
			5	No TDR - adverse event		
C097	Number_of_days_on_TDR_since_last_contact_or_session_[any_days_where_TDR_used_at_all]_NLU	int				field no longer used (NLU) entry should be null
C098	Number_of_meals_that_replaced_TDR_per_day_[on_average]_since_last_contact_or_session_NLU	int				field no longer used (NLU) entry should be null
C099	Number_of_days_of_TDR_missed_since_last_contact_or_session	int				This should be completed for every contact in TDR, FR and WMRP If a participant was planned to take TDR products but missed an entire day, enter the number of days missed here. If they are in FR and were not planned to take any products 0 should be entered
C115	Fibre_supplements_provided_for_use_until_next_planned_session_NLU	an1	Y	Fibre supplement has been provided to participant		No longer used
			N	Fibre supplement has not been provided to participant		
C116	Previously_supplied_fibre_supplements_consumed	an1	Y	Service user confirms fibre supplement has been used (entry no longer used)		Y - is no longer an acceptable response to this question and should not be used.
			F	Full		Full - The full recommended amount of fibre has been consumed (7g per day (usually issued in 2 x 3.5g portions

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			P	Partial		of Ispaghula Husk/Psyllium Husk/Fybogel) during the TDR Phase).
			N	None		Partial - Fibre has been consumed but less than the recommended amount
C104	Weight	nnn.nn		[Kilograms]		The weight of the patient in kilograms. Essential data collection points are articulated in the specification document. If there is a delay in obtaining weight prior to submission 999 can be entered as a temporary measure until actual weight can be obtained. Once correct weight obtained it should be added for next submission For digital, if more than 1 weight has been captured in the engagement period please provide the latest. If more
C105	Type_of_weight_measure	an1	O	Objective		Whether the weight of the participant has been measured by the provider, or by the participant themselves and self-reported.
C106	Date_of_Weight_Measurement	DATE YYYY-MM-DD	S	Self-reported		The date of the weight measurement
C109	Capillary_blood_glucose_test_result	nn.nn				For digital, if more than 1 blood glucose measurement has been captured in the engagement period please provide the latest
C110	Capillary_blood_test_measurement_type	an1	O	Objective		Whether the finger prick test was done by the provider, or done by the participant and then self-reported.
			S	Self-reported		
C107	Blood_pressure_(systolic_and_diastolic)	varchar(7)		Example: 120/80		This is only required for those who are on blood pressure lowering medication. For digital, if more than 1 blood pressure measurement has been captured in the engagement period please provide the latest
C108	Blood_Pressure_measurement	an1	O	Objective		Whether the blood pressure of the participant was measured by the provider, or measured by the participant themselves and then self-reported.
			S	Self-reported		
C100	Rescue_package_offered_since_last_session_or_engagement	an1	N	Not applicable		This should be completed for every contact. Please see service specification for rescue package eligibility criteria Rescue package is offered (where applicable) at a WM session (Phase_of_intervention). If accepted submit Y on session that it was accepted. If a rescue package is offered in between core sessions/engagements, the response should be added to the next session/engagement. Any sessions that take place during the RP have the phase of intervention code WMRP and this question will be N. Each participant can only have 1 rescue package (if the eligibility criteria is met) Rescue package dates are entered in the referral file. Not applicable - no weight gain (or less than the required amount), already accepted a Rescue Package, taking incompatible medication Not offered - adverse event - the participant is eligible for rescue package but it is not appropriate to offer due to an adverse event that occurred during the TDR phase meaning restarting TDR products is not appropriate Offered - accepted - the participant has been offered a rescue package and accepted the offer Offered - declined - the participant has been offered a rescue package and declined the offer (please supply reason for decline in next question) Offered - declined full, accepted partial - the participant has been offered a rescue package and declined a full rescue package, but accepted a partial (applicable to framework 1) Medication review required - the participant has been offered a rescue package and accepted however they are taking for are unsure if they are taking sulphonylureas / meglitinides / SGLT2 inhibitors therefore a The reason given by the participant for declining a Rescue Package. A participant may decline a rescue package offer more than once and each decline should be captured and applied to closest session/engagement after (if it takes place outside a core session/engagement) Please choose the most appropriate reason from the list. 'Other' should be used as a last resort only when the preceding options are not applicable.
			A	Not offered - adverse event		
			Y	Offered - accepted		
			D	Offered - declined		
			P	Offered - declined full, accepted partial		
			M	Offered and accepted but Medication review required		
C145	Rescue_Package_Reason_for_Decline	an1	1	Weight gain not deemed significant		
			2	Will reengage with weight maintenance methods		
			3	Aversion to TDR products		
			4	Inconvenient time		
			5	Other		
C101	Length_of_rescue_package	int		[Number of days]		The length of time on the rescue package since last session. This should be blank if a rescue package has not been given.
C102	Type_of_rescue_package	an1	P	Partial TDR		Please see service specification relating to the contract area regarding partial rescue packages commencement of rescue package. If the medication has been taken the participant cannot commence with the rescue package.
			2	Don't know		If the participant doesn't know whether there has been a change in their medication confirmation must be
			3	Medication taken		The purpose of this is to allow the participant to raise any non-serious adverse events they feel are significant enough to mention. It is not necessary to provide them with a list. If they answer yes, a record should be added
C113	Presence_of_any_other_diabetes_related_complications_since_last_contact	an1	Y	Participant has other diabetes related complications		New detection of a co-morbidity
			N	Participant has no other diabetes related complications		
C114	Presence_of_any_other_health_complications_since_last_contact	an1	Y	Participant has other health conditions		
			N	Participant has no other health conditions		
C111	Date_of_reschedule_attempt	DATE YYYY-MM-DD		[Date]		If the participant does not attend a session, insert the date of the reschedule attempt.
C112	Method_of_contact	int/an1	1	Letter	If session is not attended without prior warning.	This is the communication method by which the participant is contacted to re-book the session.
			2	Telephone		
			3	Text		
			4	E-mail		
			5	In person		

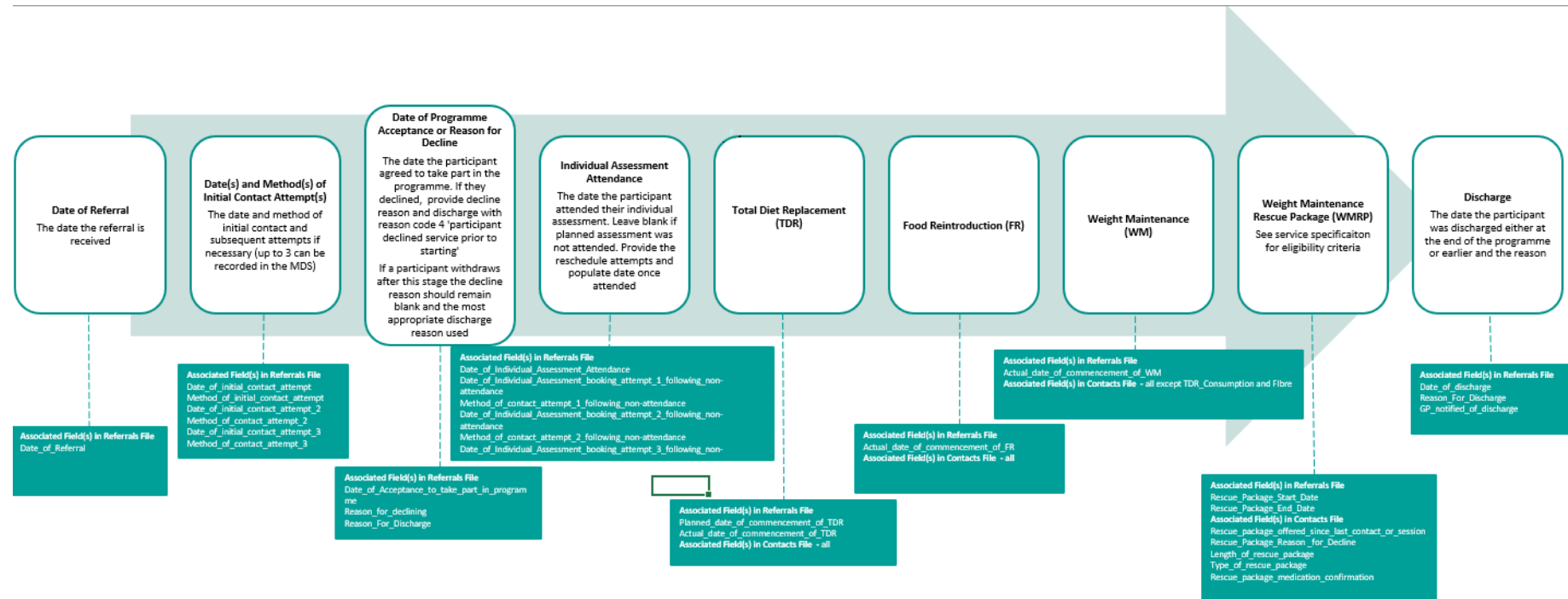
## MDS Health Incidents

Each row is a single incident - if a participant has both side effect and adverse event, submit 2 records (one for each incident)					
Unique Field ID	Field name	Format	Code	Data Values	Additional information
H117	Unique_Referral_ID	an12 (as example)			
H118	Organisation_code_of_LCD_provider	an8			
H137	Date_of_Session_or_Engagement	DATE YYYY-MM-DD			The date of the contact session at which the health incident was reported. If not at a session, the date it was reported
H119	Type_of_Health_Incident	AN2	5	Side effect	Side effects
			A	Adverse event	Adverse events as defined in the service spec
H120	Date_of_health_incident	DATE YYYY-MM-DD			Date side effect or adverse event occurred
H121	Type_of_side_effect	AN2	1	Constipation	Required entry when Type_of_Health_Incident = S
			2	Sensitivity to cold	These should be reported when it has been significant enough for the patient to mention and suspected to be a side effect of the programme (not a pre-existing condition) or severe enough to impact their TDR consumption.
			3	Headache	'Other' should only be used when none of the other options are suitable.
			4	Dizziness	Please do not combine multiple events into 'other'
			5	Fatigue	
			6	Mood change	
			7	Nausea	
			8	Diarrhoea	
			9	Heartburn / indigestion	
			10	Hair loss	
			11	Blurred Vision	
			13	Other Stomach Complaints	
			14	Skin Conditions	
			15	Illness / infection	
			12	Other	
H138	Type_of_side_effect_other	free text (AlphaNumericSpecial 50)			Where the adverse event is not listed, please provide brief summary. This should only be used where complaint is not already listed. Please ensure no PID entered here
H126	Type_of_adverse_event	an2	1	Myocardial infarction (MI)	Required entry when Type_of_Health_Incident = A
			2	Stroke	'Other' should only be used when none of the other options are suitable.
			3	Gall stones	Please do not combine multiple events into 'other'
			4	Pancreatitis	
			5	Cancer	
			6	Severe allergic reaction	
			8	Eating Disorder	
			9	Fall requiring admission	
			10	Infection / sepsis	including any infection needing hospital admission
			11	Severe constipation / impaction	
			12	Seizure	
			7	Other	

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H139	Type_of_adverse_event_other	free text (AlphaNumericSpecial 200)			Where the adverse event is not listed, please provide brief summary. This should only be used where complaint is not already listed. <b>Please ensure no PID entered here</b>
H127	Fibre_Supplement_pack_provided	AN2	Y	Yes	If additional fibre supplement has been provided in relation to side effect
			N	No	
H128	Date_fibre_Supplement_pack_provided	DATE YYYY-MM-DD			If yes, date provided
H130	Has_the_capillary_blood_glucose_flag_been_triggered	an2	Y	Yes	Please see service specification for thresholds.
			N	No	
H131	Date_capillary_blood_glucose_flag_triggered	DATE YYYY-MM-DD			If yes, date triggered
H132	Has_blood_pressure_flag_been_triggered	an2			Please see service specification for thresholds.
			H	Yes - high	BP reading meets high threshold for action
			L	Yes - low	BP reading meets low threshold for action
			N	No	
H133	Date_blood_pressure_flag_triggered	DATE YYYY-MM-DD			If yes, date triggered
H124	Serious_adverse_event_NLU	AN2	Y	Yes	Serious unintended health incidents / adverse events / side effects (major)
			N	No	
H125	Date_serious_adverse_event_occurred_NLU	DATE YYYY-MM-DD			If yes, date adverse event occurred
H122	Programme_deintensified	AN2	Y	Yes	Impact of adverse event required programme deintensification
			N	No	
H123	Date_programme_deintensified	DATE YYYY-MM-DD			If yes, date programme de-intensified
H146	Date_programme_reintensified	DATE YYYY-MM-DD			To be completed once de-intensification period has ended
H129	Any_alerts_discussed_with_Medical_Director	an2	Y	Yes	
			N	No	
H134	Number_of_unique_alerts_given_to_primary_care	numeric		[Number]	Alerts sent for all adverse events, all incidents of blood capillary glucose flag or blood pressure flag being triggered. Number entered relates to the alerts sent for the adverse event being reported. If none please submit 0
H135	Date_of_alert_given_to_primary_care	DATE YYYY-MM-DD		[Date]	
H136	Action(s)_taken	free text (AlphaNumericSpecial 200)			Please ensure no PID entered here

## Pathway Summary



## Digital Engagement Periods

Enter TDR Start Date	01-Jun-22
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### Framework 1

Week 1 begins on TDR start date (Actual\_date\_of\_commencement\_of\_TDR)

Session Number	1	1	1	1	1	1	1	2	2	2	2	2	2	2	3
Week number	1	1	1	1	1	1	1	2	2	2	2	2	2	2	3
Phase	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR
Day number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Date	01-Jun-22	02-Jun-22	03-Jun-22	04-Jun-22	05-Jun-22	06-Jun-22	07-Jun-22	08-Jun-22	09-Jun-22	10-Jun-22	11-Jun-22	12-Jun-22	13-Jun-22	14-Jun-22	15-Jun-22
Rescue Package Sessions															

### Wave 1 and Wave 2

Week 1 begins the Monday of the week TDR is started

Session Number	1	1	1	1	1	1	1	2	2	2	2	2	2	2	3
Week number	1	1	1	1	1	1	1	2	2	2	2	2	2	2	3
Phase	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR
Day number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Date (adjust TDR start date as required)	#####	#####	01-Jun-22	02-Jun-22	03-Jun-22	04-Jun-22	05-Jun-22	06-Jun-22	07-Jun-22	08-Jun-22	09-Jun-22	10-Jun-22	11-Jun-22	12-Jun-22	13-Jun-22
Rescue Package Sessions															

All digital engagements should be included within the relevant Session number, based on when they take place

Any digital engagements that take place before TDR start should be assigned to session '0'

Any digital engagements that take place after the end of week 54 should be assigned to session '100'

Rescue Package sessions should be numbered R1, R2, R3, R4 etc.

	5	5	5	5	5	5
	5	5	5	5	5	5
	TDR	TDR	TDR	TDR	TDR	TDR
	29	30	31	32	33	34
2	29-Jun-22	30-Jun-22	01-Jul-22	02-Jul-22	03-Jul-22	04-Jul-22

	5	5	5	5	5	5
	5	5	5	5	5	5
	TDR	TDR	TDR	TDR	TDR	TDR
	29	30	31	32	33	34
2	27-Jun-22	28-Jun-22	29-Jun-22	30-Jun-22	01-Jul-22	02-Jul-22

## NHS Standard Contract 2023/24

[illegible][illegible]



NHS Standard Contract 2023/24

[illegible][illegible]

## NHS Standard Contract 2023/24

[illegible][illegible]





NHS Standard Contract 2023/24

[illegible][illegible]

## NHS Standard Contract 2023/24

[illegible][illegible]

[illegible][illegible]

# NHS Standard Contract 2023/24

14	14	14	14	14	14	14	14	14	14	14	14	14	14	15	15
25	25	25	26	26	26	26	26	26	26	27	27	27	27	27	27
WM	WM	WM	WM	WM	WM	WM	WM	WM	WM	WM	WM	WM	WM	WM	WM
173	174	175	176	177	178	179	180	181	182	183	184	185	186	187	188
20-Nov-22	21-Nov-22	22-Nov-22	23-Nov-22	24-Nov-22	25-Nov-22	26-Nov-22	27-Nov-22	28-Nov-22	29-Nov-22	30-Nov-22	01-Dec-22	02-Dec-22	03-Dec-22	04-Dec-22	05-Dec-22
R3	R3	R3	R3	R3	R4	R4	R4	R4	R4	R4	R4				

14	14	14	14	14	14	14	14	14	14	14	14	14	14	15	15
25	25	25	26	26	26	26	26	26	26	27	27	27	27	27	27
WM	WM	WM	WM	WM	WM	WM	WM	WM	WM	WM	WM	WM	WM	WM	WM
173	174	175	176	177	178	179	180	181	182	183	184	185	186	187	188
18-Nov-22	19-Nov-22	20-Nov-22	21-Nov-22	22-Nov-22	23-Nov-22	24-Nov-22	25-Nov-22	26-Nov-22	27-Nov-22	28-Nov-22	29-Nov-22	30-Nov-22	01-Dec-22	02-Dec-22	03-Dec-22
R3	R3	R3	R3	R3	R4	R4	R4	R4	R4	R4	R4				



[illegible]



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NHS Standard Contract 2023/24

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## NHS Standard Contract 2023/24

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## NHS Standard Contract 2023/24

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NHS Standard Contract 2023/24

[illegible][illegible]

NHS Standard Contract 2023/24

[illegible][illegible]

## **SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS**

### **B. Data Quality Improvement Plans**

<b>Data Quality Indicator</b>	<b>Data Quality Threshold</b>	<b>Method of Measurement</b>	<b>Milestone Date</b>

## **SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS**

### **C. Service Development and Improvement Plans**

	<b>Milestones</b>	<b>Timescales</b>	<b>Expected Benefit</b>

## SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

### D. Surveys

Type of Survey	Frequency	Method of Reporting	Method of Publication
Friends and Family Test (where required in accordance with FFT Guidance)	As required by FFT Guidance	As required by FFT Guidance	As required by FFT Guidance
National Quarterly Pulse Survey (NQPS) (if the Provider is an NHS Trust or an NHS Foundation Trust)	As required by NQPS Guidance	As required by NQPS Guidance	As required by NQPS Guidance
Staff Survey (appropriate NHS staff surveys where required by Staff Survey Guidance) - the Parties agree that the nationally used NHS staff surveys are not required to be carried out by the Provider as it is not required by the Staff Survey Guidance. Notwithstanding this, the Parties agree that the Commissioner will instruct the Provider of the matters to be covered in a Staff Survey, the frequency and method of reporting and/or publication from time to time during the Term and the Provider agrees to carry out the Staff Survey in accordance with those instructions	As required by The Commissioner	As required by The Commissioner	As required by The Commissioner

## **SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS**

### **E. Data Processing Services**

**Not applicable**

## **SCHEDULE 7 – PENSIONS**

**Not Applicable**



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