# Protocol details

## PROTOCOL TITLE:

GLP-1/GIP receptor agonists in UK surgical patients: a prospective observational multicentre service evaluation

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# List of Abbreviations and Definitions

AE Adverse Event

AR Adverse Reaction

ASR Annual Safety Report

CA Competent Authority

CI Chief Investigator

CRF Case Report Form

CRO Contract Research Organisation

DMC Data Monitoring Committee

e-CRF Electronic Case Report Form

EC European Commission

GLP-1RA Glucagon Like Peptide-1 Receptor Agonist

GIP-RA Gastric Inhibitory Polypeptide Receptor Agonist

GAfREC Governance Arrangements for NHS Research Ethics Committees ICF Informed Consent Form

MA Marketing Authorisation

MS Member State

PI Principle Investigator

Participant An individual who takes part in a clinical trial

QA Quality Assurance

QC Quality Control

SAD Supraglottic airway device

SAE Serious Adverse Event

SDV Source Document Verification

SOP Standard Operating Procedure

SSA Site Specific Assessment

TMG Trial Management Group

TSC Trial Steering Committee

# Summary/Synopsis

|  |  |
| --- | --- |
| Title | GLP-1/GIP receptor agonists in UK surgical patients: a prospective observational multicentre service evaluation |
| Protocol Short Title/Acronym | GLIMPSE: GLP-1/GIP receptor agonist Management in the Perioperative Setting |
| Protocol Version number and Date | v1 (26/02/25) |
| Study Duration | 2 weeks |
| Lead Site | Guy’s and St. Thomas’ NHS Foundation Trust |
| Chief Investigator | Kariem El-Boghdadly |
| Medical condition or disease under investigation | Glucagon Like Peptide-1 (GLP-1) and Gastric Inhibitory Polypeptide (GIP) Receptor Agonist (RA) drugs in surgical patients |
| Purpose of service evaluation | Identify current usage of GLP-1/GIP RAs in surgical patients and outcomes associated with their use |
| Primary objective | To determine the proportion of patients undergoing elective and emergency procedures who are established on GLP-1/GIP receptor agonists preoperatively |
| Secondary objective(s) | * To describe the airway management techniques used for patients established on GLP-1/GIP RAs * To measure the incidence of perioperative dysglycaemic episodes in patients on GLP-1/GIP RAs * To measure the incidence of pulmonary aspiration in patients on GLP-1/GIP RAs * To describe local hospital guidelines regarding the management of GLP-1/GIP RAs and compliance with these guidelines |
| Number of Subjects/Patients | Convenience sample |
| Study Type | Service evaluation |
| Endpoints | *Primary Endpoint*   * Rate of pre-operative GLP-1/GIP RA use   *Secondary Endpoints*   * Dysglycaemia * Pulmonary aspiration |
| Main Inclusion Criteria | Adult patients on GLP-1/GIP receptor agonists requiring anaesthetic care for a procedure during the pre-defined study window (as defined by this study, see ***Section 7***) within participating hospitals |
| Data collected/storage (if applicable) | Anonymised data will be stored on a REDCap secure data capture server. |

# Introduction

Incretin therapies, such as glucagon-like peptide-1 receptor agonists (GLP-1 RA) and dual glucagon-like peptide-1 and glucose-dependent insulinotropic polypeptide receptor agonists (GLP-1/GIP RAs), are medications increasingly used to treat diabetes and obesity(as summarised in ***Table 1***).1 There are concerns that the perioperative use of these drugs may be associated with perioperative risk. Reports suggest that the use of GLP-1 RAs and GLP-1/GIP RAs may increase the risk of pulmonary aspiration due to delayed gastric emptying.2–4  While the potential risk of pulmonary aspiration is yet to be reliably determined in the literature, the number of patients taking these medications is also currently unknown. There is increasing anecdotal evidence in the UK, highlighted in a recent statement by the medical director of NHS England, that these medications are being obtained through online pharmacies for aesthetic reasons and therefore may not be listed on patients’ medical records or divulged pre-operatively.5

The pharmacodynamics of incretin therapies are directly related to the risks posed. GLP-1/GIP are endogenous incretins. GLP-1 stimulates insulin release and suppresses glucagon release,6 and also slows gastric emptying, thereby increasing satiety, reducing oral intake, lowering blood glucose levels, and encouraging weight loss.7 The individual contribution of GIP is hard to identify but it is possible that it works mainly through potent activation of GLP-1.1 The suppression of gastric peristalsis may put patients at risk of pulmonary aspiration, particularly within the first 12 weeks of treatment.6 Other adverse effects reported include gastrointestinal symptoms, hypoglycaemia, pancreatitis, and allergic reactions.8

The population vulnerable to these potential risks continues to expand as incretin therapies are used for an increasing number of conditions. Incretins are recommended by the National Institute for Health and Care Excellence (NICE) for the management of insulin-dependent and non-insulin dependent diabetes.9 GLP-1 RAs also have benefits beyond lowering of glucose. They reduce the risk of cardiovascular events and also result in weight loss and a reduction in obesity-related comorbidities.6 The recent SURMOUNT-1 and SURMOUNT-2 trials have demonstrated weight loss in obese patients without diabetes and they are now being used as a treatment for obesity in those without a diagnosis of diabetes.6 Prescribing of GLP-1 RAs has increased to the extent that there has been national shortages of one form of this medication in the UK.10

The increased prescribing of these medications and their unquantified risk make the need for perioperative management guidelines clear. Unfortunately, recommendations are conflicting and this is likely a reflection of the current paucity of evidence in this area. The American Society of Anesthesiologists (ASA) recommend holding daily dosed preparations of GLP-1 RAs the day before surgery and on the day of surgery, and holding weekly preparations for one week before surgery.11 This is at odds with current Centre for PeriOperative Care (CPOC) and Association of Anaesthetists (AoA) guidance which recommends that GLP-1 RAs, and by extension all currently available incretin therapies, be continued.12

This prospective, national, multicentre, service evaluation aims to: (1) estimate the proportion of the population taking these medications and (2) understand and quantify the peri-operative risks that patients taking these medications may encounter. We aim to contribute to the literature by reporting the proportion of surgical patients that are established on these medications, and describing their perioperative management and outcomes.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **GLP-1 receptor agonists** | | | | | |  | **GIP receptor agonist** |
|  | **Exenatide (twice daily)** | **Lixisenatide**  **(once daily)** | **Liraglutide**  **(once daily)** | **Exenatide**  **(once weekly)** | **Albiglutide**  **(once weekly)** | **Dulaglutide**  **(once weekly)** | **Semaglutide** | **Tirzepatide**  **(once weekly)** |
| Administration route | SC | SC | SC | SC | SC | SC | SC (weekly) or oral (Lucas, #8514) | SC |
| **Pharmacokinetics** | | | | | | |  |  |
| Total Dose range (for diabetes and / or obesity) | 10 µg – 20 µg | 10 μg - 20 μg | Diabetes 0.6 mg - 1.8 mg  Weight loss 0.6 – 3.0 mg | 2 mg | 30 mg - 50 mg | 0.75 mg – 4.5 mg | Diabetes (weekly sc): 0.25 mg – 1 mg  Diabetes (oral)  3 mg – 14 mg  Weight loss (weekly sc)  0.25 – 2.4mg weekly | Diabetes or weight loss 2.5 mg – 15 mg weekly |
| AUC (after single dose) | 247 pM/h | NS | 256 pM/h | NS | 465 μg.h/mL | 14,000 ng.h/mL | 2,600nmol.h/L | 43,459–63,467 ng.h/mL |
| Cmax | 50 pM |  | 9 nM | 55 pM | 1.74 μg/ml | 114 ng/mL | 10.3 nmol/L | 1250 ng/ml |
| Tmax (h unless stated otherwise) | 2.1 | 1–3.5 | 10–14 | 6–7 weeks | 3–5 days | 48 | 24 | 24 |
| Bioavailability (%) | 65–76 |  | 55 | 65–76 | NS | 65 (0.75 mg)  47 (1.5 mg) | 0.8% (oral)  89% (SC) | 80 |
| Volume of distribution (L) | 28.3 | 100 | 13 | 28.3 | 11 | 19.2 (0.75 mg)  17.4 (1.5 mg) | 8 | 10.3 |
| Fraction bound to plasma protein, % | NS | 55 | >98 | NS | NS |  | >99 | >99 |
| Elimination half-life (t1/2)  (h unless stated otherwise) | 2.4 | 3 | 13 | 2.4  (as for exenatide) | 5 days | 4.5 days (0.75 mg)  4.7 days (1.5 mg) | 7 days | 5 days |
| Major elimination route | Renal/ proteolysis | Renal/ proteolysis | Metabolised | Renal/proteolysis | Metabolised | Metabolised | Metabolised | Metabolised |
| Dose reduction with Renal Impairment | Mild RI, no  Moderate RI, caution with dose increase  ESRD/severe RI, not recommended | Mild RI, no  Moderate RI, caution  ESRD/severe RI, not recommended | Mild RI, no  Moderate RI, no  ESRD/severe RI, not recommended | Mild RI, no  Moderate RI, not recommended  ESRD/severe RI, not recommended | Mild RI, no  Moderate RI, no  ESRD/severe RI, not recommended | Mild RI, no  Moderate RI, no  ESRD/severe RI, not recommended | No dose change necessary (but not recommended in ESRD) | No dose change necessary (but not recommended in ESRD) |
| Active metabolite | No | No | No | No | No | No | No | No |

**Table 1.** List of glucagon-like peptide-1 (GLP-1 RA) and glucose-dependent insulinotropic polypeptide receptor agonists (GIP RA) with a summary of relevant pharmacokinetics

# Trial objectives and purpose

##### Aims

1. To determine the prevalence of GLP-1/GIP RA use in the UK surgical population
2. To describe how patients on GLP-1/GIP RAs are managed perioperatively
3. To estimate the incidence of complications related to continuing or stopping GLP-1 receptor agonists during the perioperative period

# Study design & Flowchart

## Study Design

GLIMPSE is a service evaluation exploring the risks associated with preoperative use of GLP-1/GIP RAs for patients undergoing elective and emergency procedures within NHS trusts in the UK. Adult patients established on a GLP-1/GIP RAs and undergoing a procedure requiring the care of an anaesthetist will be eligible for enrolment into the study. The study duration will encompass a 15-day period where patients are enrolled over 14 consecutive days with a further 1 additional day for follow-up data collection. Individual sites are free to choose their own data collection window which is locally convenient between the xxx and the xxx, provided enrolment into the study begins on a Monday and completes on day 14.

##### Primary outcomes:

* To determine the proportion of patients undergoing elective or emergency procedures taking GLP-1/GIP RAs preoperatively

##### Secondary outcomes:

* To describe the airway management techniques used for patients established on GLP-1/GIP RAs
* To measure the incidence of perioperative dysglycaemic episodes in patients established on GLP-1/GIP RAs
* To measure the incidence of pulmonary aspiration in patients established on GLP-1/GIP RAs
* To describe local hospital guidelines regarding the management of GLP-1/GIP RAs and compliance with these guidelines

# List selection

Operating lists from all participating NHS hospitals will be included, with patients from those lists being eligible. Both elective and emergency cases will be included. The centres and local investigators will be identified by the Pan-London Perioperative Audit and Research Network (PLAN) and other participating trainee research networks.

Data will be collected over a continuous 14-day period (07:30 Monday until 07:29 on the second Monday following). For all cases, the start time of the procedure will be the time point of the first set of observations on the anaesthetic chart and used to identify those patients to include.

## Patient inclusion criteria

* + - Adult patients (≥ 18 years of age) with preoperative use of a GLP-1/GIP RAs
    - Undergoing a procedure (interventional or diagnostic) requiring the care of an anaesthetist

## Patient exclusion criteria

* + - Paediatric patients (< 18 years of age)
    - Patients where their anaesthetic care starts outside of the operating theatre complex
    - Patients having obstetric procedures (pregnant patients undergoing non-obstetric surgery will be included)
    - First set of observations outside the 14-day enrolment period

# Project procedures

## Patient inclusion

Patients will be identified as eligible by local investigators using methods specific to the centre, involving published operating lists and emergency theatre bookings. All eligible patients will be included if possible.

# Data

## Data to be collected

Data will be collected on all operating lists with patients who meet inclusion criteria in participating hospitals. Each hospital taking part will have nominated staff who will be responsible for data collection.

For each day of the study the local investigating team will determine the total number of patients eligible for inclusion.

Patients established on GLP-1/GIP RAs pre-operatively will be identified by the primary anaesthetist through assessment and review of medical records as per routine clinical care. For patients taking any form of GIP/GLP-1 RA, data regarding the specific drug, route, dose, indication, when it was started, and whether it was held preoperatively (and if so for how many days preoperatively) will be collected. In addition, data on anaesthesia type, airway management techniques, episodes of pulmonary aspiration or regurgitation will be collected. Any episode of dysglycaemia occurring either intraoperatively or in the 24 hours postoperatively will be recorded, this will be achieved by reviewing the medical records of all patients meeting the inclusion criteria 24 hours later. Data will be collected from the patients’ hospital medical records and recorded on a paper case record form (CRF 1; appendix 1) by an anaesthetist involved in the case or by a member of the local investigating team. A summary of intended data for collection is available in **Table 2**.

Completed CRFs will be collected from the treating anaesthetic team. Local investigators will be responsible for following up patient records for 24 hours postoperatively to report episodes of dysglycaemia, and in ensuring accuracy and completeness of data. Where appropriate, this should include cross-checking with patient notes and other sources of information.

Completed CRFs will be stored in a secure location accessible by the local PI and other named members of the study team in accordance with NHS Information Governance standards. Information from each paper CRF, as well as the total number of eligible patients for each day of the project, will be entered via a secure web-based portal onto a secure database. The database will have data validation rules built-in to ensure accurate data entry (e.g. range checks, and field validation).

No patient-identifiable information will be uploaded to the secure database. Each site may elect to use a local ID upon the CRF to facilitate retrospective data capture within the immediate time frame of the project, however this should be detached once the CRF is completed and will not form part of the dataset uploaded to the data capture server. Paper CRFs will be retained by the local study team in a locked, secure location in the hospital for a period of 6 months after the project ends to allow queries about study quality to be addressed during data cleaning and analysis. The local ID will not remain upon the CRF during this period.

Additionally, the lead for each site will submit, via the online REDCap system, the study weeks that site has selected (from one of weeks commencing xxx), the total number of eligible procedures for each 24 hour period of the study, and the list of all local investigators involved in the study (to enable production of certificates to demonstrate involvement as well as to allow naming of all collaborators on any manuscripts arising from the study). The site details data capture form is provided in ***Appendix x***.

All investigators and any other individuals contributing to the study will be required to comply with the Data Protection Act 2018 and the NHS code of confidentiality.

|  |
| --- |
| **Baseline data** |
| * Site (automatically populated dependent upon the login credentials of the local investigator) * Day of the study (1 to 14) * Age of patient (grouped into 18-29, 30-39, 40-59, 60-79 and ≥ 80 years) * Biological sex of patient * American Society of Anesthesiologists (ASA) physical status (1-5) * Patient body mass index (BMI), grouped into underweight (< 18.5 kg/m2), normal (18.5 – 24.9 kg/m2), overweight (25.0 – 29.9 kg/m2), class 1 obesity (30.0 – 34.9 kg/m2), class 2 obesity (35.0 – 39.9 kg/m2), class 3 obesity (>= 40.0 kg/m2) |
| **Perioperative data** |
| * Surgical urgency (elective; expedited; urgent; emergency) * Start time of procedure (first set of observations entered into the anaesthetic record), grouped into daytime (07:30–17:59); evening (18:00–23:59); and overnight (00:00–07:29) * Surgical specialty * Surgical severity (minor; intermediate; major) * Anaesthetic: General anaesthesia, sedation, regional anaesthesia * Grade of anaesthetist managing airway, if applicable (initial airway manager and second airway manager if required) * Airway management technique: pre-oxygenation, mask ventilation, apnoeic oxygenation * Airway devices utilised: facemask, supraglottic airway device (1st or 2nd generation); tracheal tube; other (including rigid bronchoscope, jet ventilator and transnasal humidified rapid-insufflation ventilatory exchange) * Use of cricoid force * Use of gastric ultrasound * Induction: intravenous routine, intravenous RSI, inhalational * Did the anaesthetic plan change in light of GLP-1RA use? (Yes/No) * Regurgitation of gastric contents\*\*- Induction/maintenance/emergence * Pulmonary aspiration\* - Induction/maintenance/emergence * Unplanned admission- Hospital/Critical Care * Reintubation * Death (within 24 hours) |
| **Risk factors for Aspiration** |
| * History of:   + Bowel obstruction   + Recent trauma   + Pre-operative use of opioids   + Raised intracranial pressure   + Pregnancy   + Previous upper GI surgery (e.g. Oesophagectomy, total/partial gastrectomy, oesophagogastrectomy, bariatric surgery)   + Hiatus hernia   + Gastro-oesophageal reflux disease   + Obesity   + Pain   + Renal failure   + Gastroparesis   + Inadequately fasted for procedure |
| **Data related to GLP-1 RA use** |
| * Drug name(s), dose, frequency, route, indication(s) (e.g. diabetes/weight loss), duration (<1 month, 1-3 months, 3-6 months, 6-12 months, >12 months), last dose. * Fasting status at time of anaesthetic start- hours since last solid ( <6 hrs, 6-12 hrs, 12-24 hrs, >24hrs), and hours since last clear fluid (<2 hrs, 2-6 hrs, 6-12 hrs, >12 hrs) * Medical history- Diabetes (Type1/type 2), obesity, heart failure, renal failure * Hypoglycaemia event = Single event of BM < 4 mmol/L * Hyperglycaemia event = Single event of BM > 12 mmol/L * Number of blood glucose measurements performed within the 24 hour follow up period * Anti-diabetic medications   + Tablet-based: Acarbose, Meglitinide, Metformin, Sulphonylurea, Pioglitazone, DPP4 inhibitors, SGLT-2 inhibitors and whether these were held pre-op (Yes/No)   + Insulin-based: Long-acting insulin, intermediate-acting insulin, short-acting insulin and whether these were held pre-op (Yes/No)   + Use of variable rate insulin infusion (sliding scale insulin) * Local guidance for the perioperative management of GLP-1/GIP RA (Yes/No), local guidance recommends preoperative cessation of GLP-1/GIP RA? (Yes/No). If yes, number of days cessation for daily GLP-1/GIP RA, and number of days cessation for once weekly preparation. |

**Table 2.** Summary of data to be collected by local investigators. \*Aspiration event: Pulmonary aspiration will be defined as: the confirmed or suspected inhalation of oropharyngeal or gastric contents into the larynx and lower respiratory tract [10]. \*\*Regurgitation: defined as the observed passage of gastric contents into the oropharynx.

## Data handling and record keeping

All investigators and study staff will be required to comply with the requirements of the Data Protection Act 2018 with regard to the collection, storage, processing and disclosure of personal information and will uphold the Act’s core principles.

Data will be collected onto paper CRFs by either local investigators or the anaesthetic team involved with the case. If local IT capabilities permit, data may be directly uploaded to the data capture service. Local investigators will also upload the total number of patients screened for GLP-1/GIP receptor agonist use and the total number of eligible patients for each 24 hour period of the study to identify capture rate.

Data will be uploaded by local investigators to a secure data capture server, the interface will use the REDCap v10.4.1 electronic CRF software. A REDCap ID for each patient included will be provided by the system for each new e-CRF uploaded. No uploaded data will contain patient-identifiable information.

All collected data will be anonymised. The following steps have been undertaken to ensure that patients cannot be reidentified from the collected data:

1. All ages are collected in bands.
2. No specific operation/procedure name is collected.
3. The date of surgery is not specifically collected, purely the day of the week upon which it took place during the chosen data collection period.
4. No name, hospital number or NHS number is uploaded to the data collection server.
5. All sites are required to register the service evaluation with local Clinical Governance departments prior to recruitment to ensure any local issues are handled appropriately.
6. Caldicott Guardian approval at the lead site will be obtained (available to sites upon request)
7. Information Governance approval at the lead site will be obtained (available to sites upon request).

# Statistical considerations

## Sample size calculation (some pilot/feasibility studies may not require a formal sample size calculation)

This is a service evaluation which aims to describe the current rate of GLP-1/GIP receptor agonist use and associated outcomes, and therefore a sample size calculation is not applicable.

## Statistical analysis

Descriptive statistics will be used. Continuous data will be reported using means (standard deviation, SD) or medians (interquartile ranges [range]) where appropriate. Categorical data will be reported as numbers (percentages, %) with 95% confidence intervals (CI) calculated using an appropriate method, where applicable. A p value of < 0.05 will be considered as statistically significant.

# Ethical considerations

This study is designed as a service evaluation, and no ethical approval is expected to be required. As we are collecting routinely captured data with no patient identifiable data, and will not involve either direct patient contact or influence their care in any way, no patient consent will be required. Approval from the Caldicott Guardian at the lead site (Guy’s and St. Thomas’ NHS Foundation Trust, London, UK), and audit registration at all recruiting centres will be required prior to commencing the project. Participating hospitals will ensure that their local investigators will be appropriately trained, but no GCP certification will be required from investigating teams as this is a service evaluation. The local PI will ensure that no patient identifiable information will be stored during the study.

# Financing and Insurance

No funding will be required for this study. All investigators will be NHS employees working in their respective trusts and standard NHS Indemnity will apply.

# Reporting and dissemination

Where possible, we plan to present the results of the project in peer-reviewed journals or other conference presentations to communicate findings to the community and provide updates on potential best practices for personnel risk mitigation. The anonymised dataset will be made available to other researchers within the field upon reasonable request.

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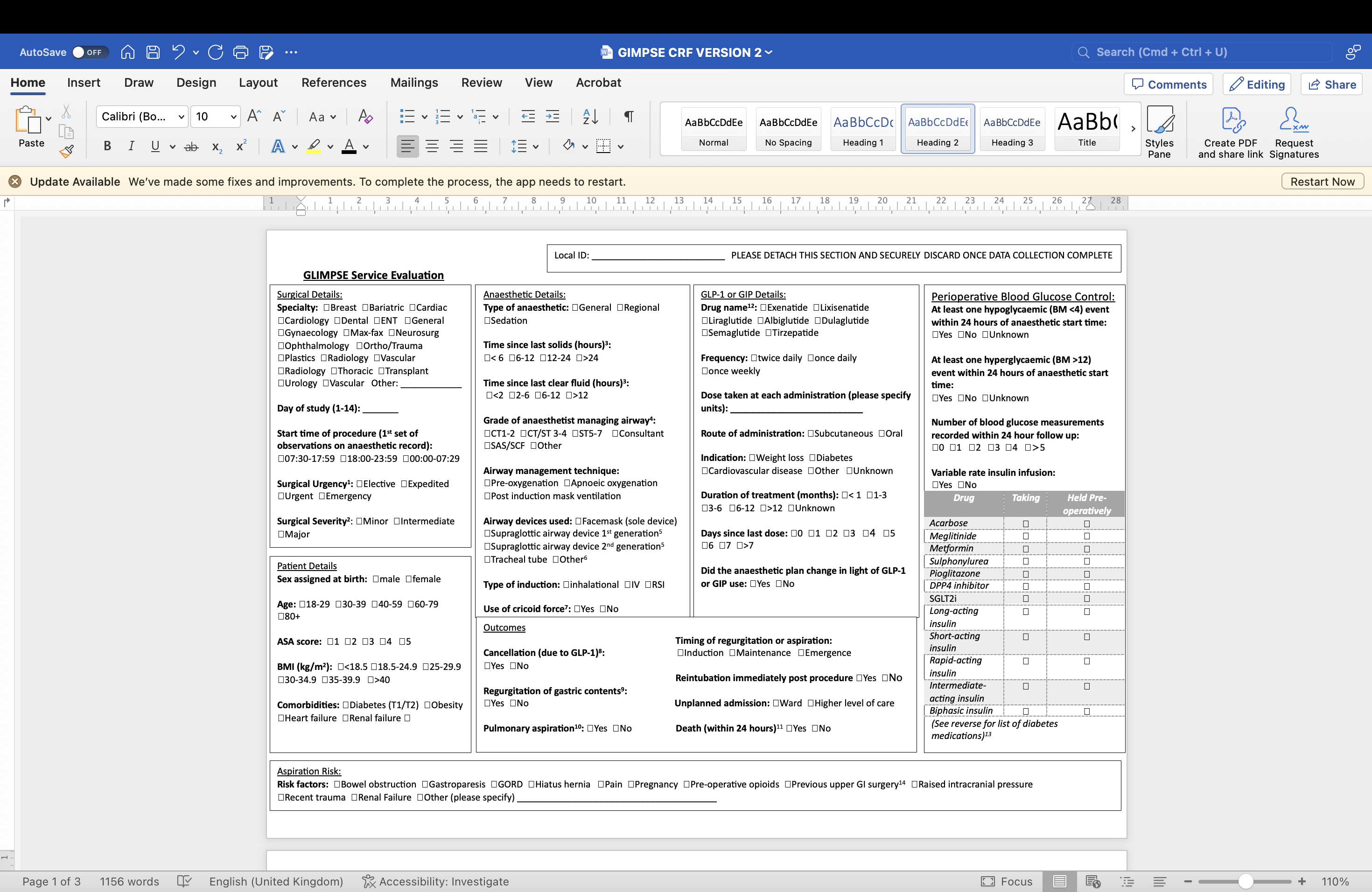
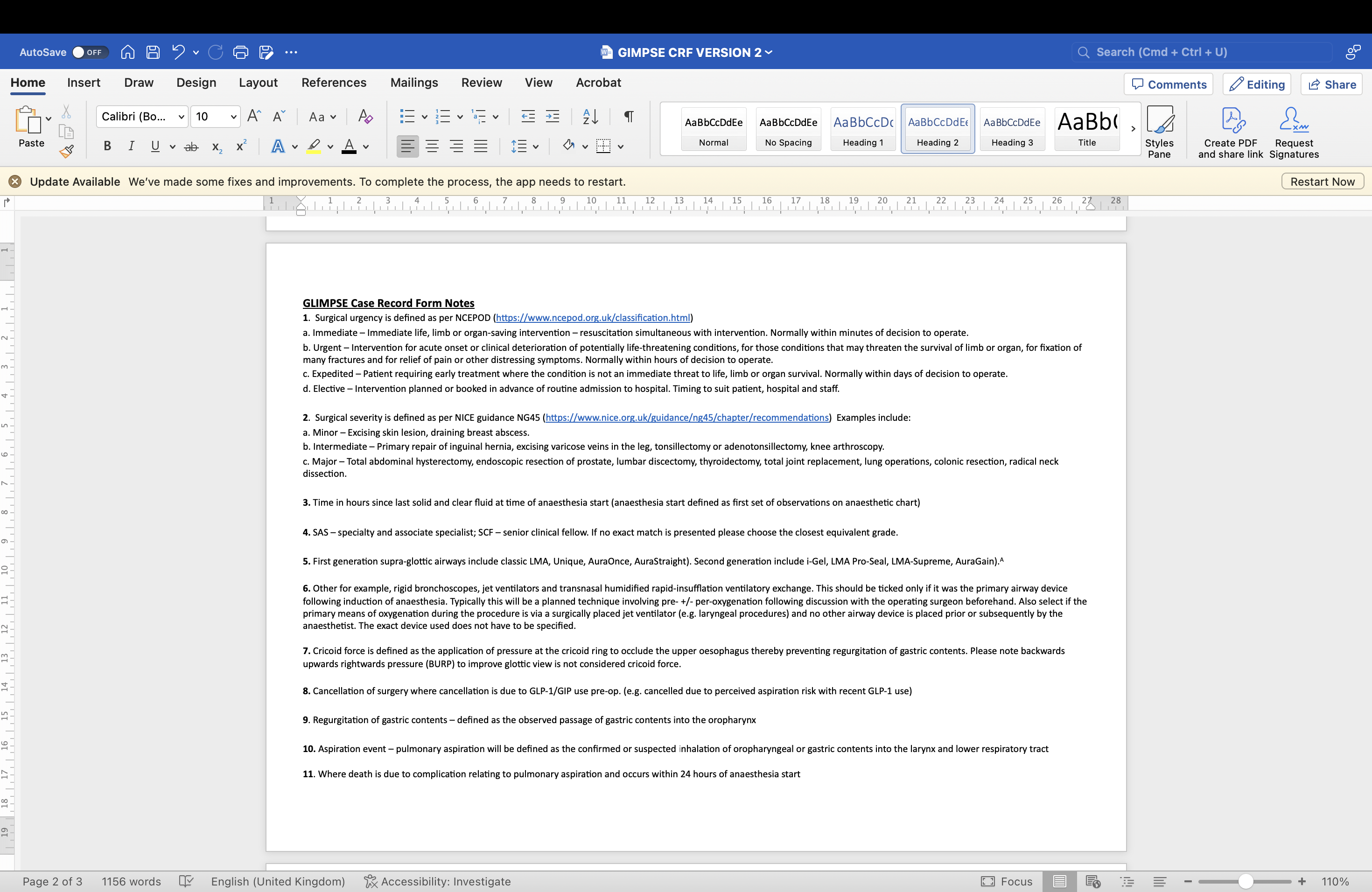
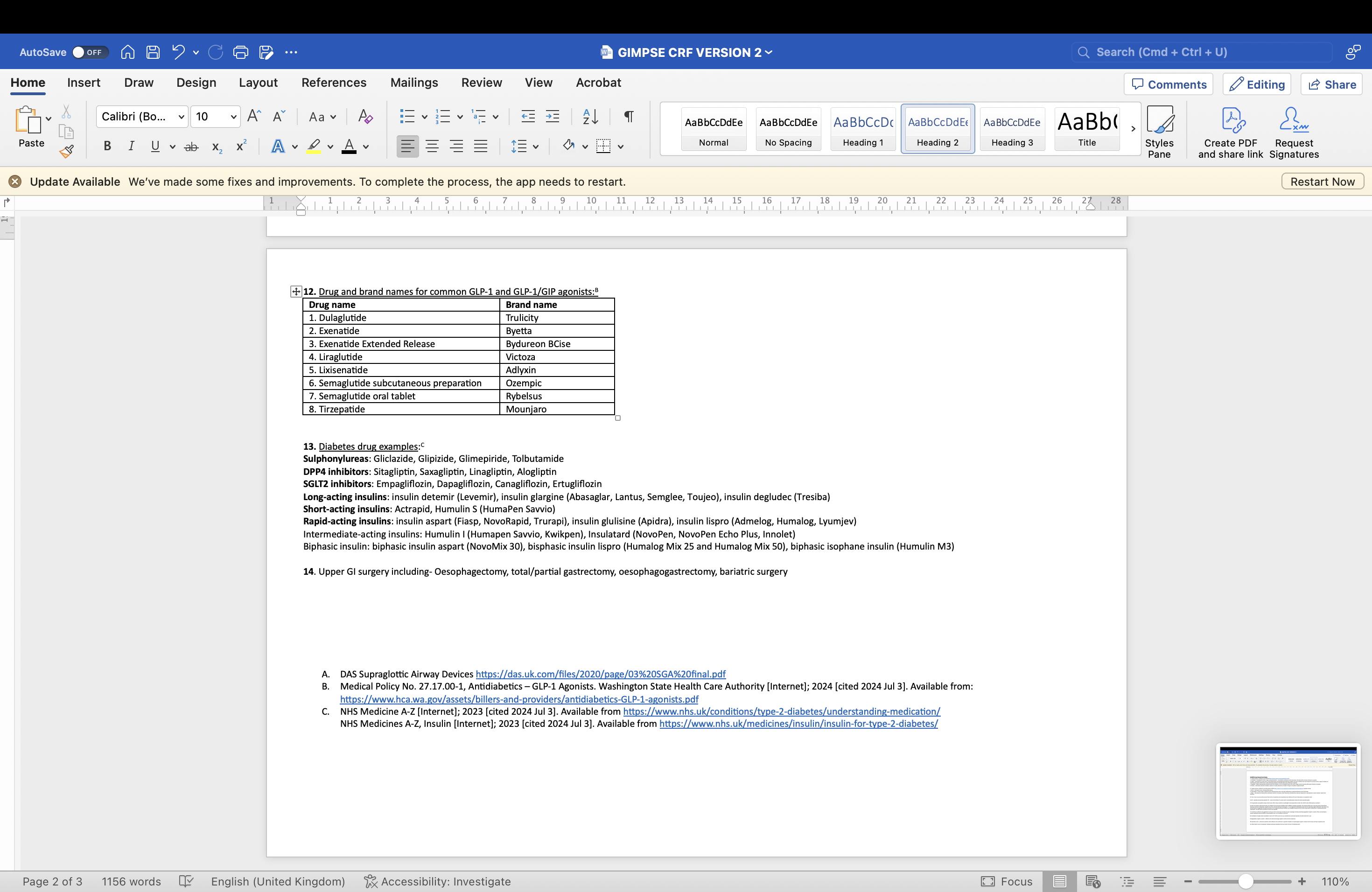
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# Appendices

# Appendix 1 - Protocol amendment / Revision history

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Version Stage** | **Version No.** | **Version Date** | **Protocol updated & finalised by** | **Appendix No.**  **Detail the reason(s) for the protocol update** |
|  | **V1** | **12/07/24** | **T Potter**  **K. El-Boghdadly**  **J Cronin**  **F Beatty**  **J Kua**  **D Wong**  **A McKechnie** | **First draft** |
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