Non-interventional study report

Study ID: NN8022-4241

In-market utilisation of liraglutide used for weight management in Europe: a retrospective medical record review study

PASS information

Title	In-market utilisation of liraglutide used for weight management in Europe: a retrospective medical record review study
Version identifier of the final study report	1.0
Date of last version of the final study report	04 October 2019
EU PAS register number	EUPAS16225
EU PAS register link	http://www.encepp.eu/encepp/viewResource.htm?id=16544
Active substance	Liraglutide (ATC code: [redacted])
Medicinal products	Saxenda® Victoza®
Product reference	Saxenda®: EMEA/H/C/003780 Victoza®: EMEA/H/C/001026
Procedure number	Saxenda®: EMEA/H/C/003780/MEA14
Marketing authorisation holder(s)	Novo Nordisk
Joint PASS	No
Research question and objectives	To investigate in-market utilisation of liraglutide used for weight management in: • Italy only: Use of Saxenda® according to approved indication. • Italy and Germany: Use of Victoza® for weight management. • Italy only: Use of Saxenda® according to approved posology.
Country(-ies) of study	Two European Union (EU) countries (Germany and Italy)
Author	[redacted]
UTN	U1111-1185-3661
ClinicalTrials.gov identifier	NCT02967757
Generic name	Liraglutide
Indication	Saxenda®: Weight management Victoza®: Type 2 Diabetes
Investigator(s)	There were 41 physicians appointed as individual overall responsible at each of the sites in the study – one at each study site.
Study site(s)	25 sites in Italy and 16 sites in Germany
Study initiated	22 December 2016
Study completed	28 May 2019

Lead study manager	[redacted]
Study manager(s)	[redacted]
Epidemiologist	[redacted]

Marketing authorisation holder(s)

Marketing authorisation holder(s) (MAH(s))	**Novo Nordisk A/S** **Novo Allé** **DK-2880 Bagsværd** **Denmark**
MAH contact person	[redacted]

This study was conducted in accordance with the Declaration of Helsinki (64th WMA General Assembly) and the Guidelines for Good Pharmacoepidemiology Practices (initially issued: 1996. Revision 2, April 2007).

Table of contents

List of in-text figures

Page

List of in-text tables

1 Abstract

Please refer to separate document

2 List of abbreviations and definitions of terms

BMI	Body Mass Index
CRA	Clinical Research Associate
CRF	Case Report Form
CV	Curriculum Vitae
DMP	Data Management Plan
DUS	Drug Utilisation Study
EDC	Electronic Data Capture
EMA	European Medicines Agency
EU	European Union
EU PAS	The EU electronic register of Post-Authorisation Studies maintained by the European Medicines Agency
FAS	Full Analysis Set
GORD	Gastro-Oesophageal Reflux Disease
GLP-1	Glucagon-Like Peptide-1
GP	General Practitioner
GPP	Guidelines for Good Pharmacoepidemiology Practices
GVP	Good Pharmacovigilance Practice
ICF	Informed Consent Form
IEC	Independent Ethics Committee
IRB	Institutional Review Board
MAH	Marketing Authorisation Holder
PASS	Post Authorisation Safety Study
[redacted]	
RMP	Risk Management Plan
SAP	Statistical Analysis Plan
SD	Standard Deviation
SmPC	Summary of Product Characteristics
SOP	Standard Operating Procedure
T2DM	Type 2 Diabetes Mellitus
TLF	Table, Listing and Figure
UTN	Universal Trial Number
WHO	World Health Organization

3 Investigators

Physicians should not be identifiable in the report.

4 Other responsible parties

Sponsor

Novo Nordisk A/S served as the sponsor of this study. It was the responsibility of Novo Nordisk A/S to ensure proper monitoring of the study and compliance with all applicable regulatory guidelines and regulations.

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

Study Coordination

Novo Nordisk A/S has engaged [redacted] specialised in post-marketing studies, to provide scientific leadership and to conduct the study. [redacted] designed and conducted the study with review and input from Novo Nordisk.

[redacted]

5 Milestones

Table 5-1 Milestones

Milestone	Actual date
Study initiation	22 December 2016
Study completion	28 May 2019
Registration in the EU PAS register	06 December 2016
Pilot study report	17 November 2017
Final report of study results	04 October 2019

6 Rationale and background

Saxenda® and Victoza® are both medicinal products containing the active substance liraglutide. Liraglutide is a long-acting glucagon-like peptide-1 (GLP-1) analogue (incretin mimetic), which has been shown to reduce hyperglycaemia in patients with type 2 diabetes mellitus (T2DM). The mechanisms of action for liraglutide include stimulation of insulin secretion and decrease of glucagon secretion, both in a physiological and glucose dependent-manner. The effects of liraglutide also include reduced sensation of hunger and increased satiety, leading to decreased food intake, thus contributing to subsequent weight loss (1,2).

Victoza® is indicated for the treatment of adults with T2DM as an adjunct to diet and exercise at doses of 1.2 mg and 1.8 mg and received marketing authorisation from the European Medicines Agency (EMA) in June 2009. Saxenda® (liraglutide 3.0 mg) is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adults with obesity (Body Mass Index [BMI] ≥30 kg/m²), or in adults with overweight (≥27 kg/m² to <30 kg/m²) and at least one weight-related comorbidity, such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea. The efficacy of Saxenda® was demonstrated in five phase 2 and/or phase 3 clinical trials (1). These trials involved around 5,800 patients with overweight/obesity, which consistently showed that patients administered Saxenda® achieved clinically relevant placebo-subtracted sustained weight loss, with a greater proportion of patients achieving at least 5 and 10% weight loss when administered Saxenda® compared to placebo. Saxenda® received marketing authorisation from the EMA in March 2015.

As defined in the Risk Management Plan (RMP) for Saxenda®, a retrospective drug utilisation study (DUS) to investigate patterns of use of Saxenda® and Victoza® in routine clinical practice has been requested by the EMA as a post marketing requirement. As is the case with any medicinal product, real-world use of Saxenda® or Victoza® may differ from the approved indication or recommendations outlined in the Summary of Product Characteristics (SmPC) (1,2). Considering that these two liraglutide products with the same strength and formulation are available for different indications with different doses, there is the potential for inadvertent use of the other product for either indication. The DUS allowed the assessment of usage patterns of liraglutide for weight management, and thereby could refine pharmacovigilance planning and risk management.

Prior to the current DUS which is referred to as the full study throughout this document, a pilot study was conducted 6 months after launch of Saxenda® in Germany and Italy. Saxenda® was launched on 27th January 2016 in Italy and on 1st April 2016 in Germany. The objective of the pilot study was to evaluate the feasibility of the full DUS. The feasibility was evaluated on three main parameters: (1) possibility of identifying physicians prescribing Saxenda®/Victoza® and participating sites; (2) possibility of identifying patients treated with Saxenda® or Victoza® and (3) availability and quality of the variables used to determine the specified endpoints (see Section 7). The results of the pilot study are described in Appendix 16.3. Based on the feasibility data obtained in the pilot study, refinements were necessary before the full study was implemented in the two

countries. A major finding of the pilot study was the inability to recruit enough Saxenda® prescribers in Germany due to low market penetration and reluctance of sites to participate. The protocol of the DUS was adjusted in consequence, by including only Victoza® patients in Germany. In the pilot study, it was also observed that different questions related to doses such as the question on "target dose" and the questions on repeat prescription dates were not well understood by the sites. The question on "target dose" was therefore replaced by the wording "final dose" and the questions on repeat prescription dates were removed and only questions related to dose changes remained. The pilot study also revealed that patients could be prescribed Saxenda® for weight-related comorbidities other than dysglycaemia, hypertension, dyslipidaemia or obstructive sleep apnoea. The DUS was adjusted accordingly by adding an open question for weight-related comorbidities so that comorbidities other than dysglycaemia, hypertension, dyslipidaemia and obstructive sleep apnoea could be reported.

The full study was conducted in accordance with the Declaration of Helsinki (64th WMA General Assembly), the Guidelines for Good Pharmacoepidemiology Practices (initially issued: 1996. Revision 2, April, 2007) and with Good Pharmacovigilance Practice (GVP). Prior to study initiation, the protocol, its amendments and patient information/informed consent forms were reviewed and approved by an independent ethics committee (IEC)/institutional review board (IRB) (16 IECs in Germany and 25 IECs in Italy). The IECs/IRBs were transparent in their functioning, independent of the researcher, the sponsor and any other undue influence, and duly qualified. Patient enrolled in the study have received the patient information sheet and informed consent form prior data entry could commence. In Italy patients also received a general practitioner (GP) letter to be forwarded to their family doctor.

A list of the IECs/IRBs that reviewed and approved the protocol, including approval dates is in Appendix 16.1.3.

7 Research question and objectives

The aim of this full study was to investigate in-market utilisation of liraglutide for weight management.

Saxenda® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for weight management in adult patients with an initial BMI of

- ≥ 30 kg/m² (obese), or
- ≥ 27 kg/m² to < 30 kg/m² (overweight) in the presence of at least one weight-related comorbidity such as dysglycaemia (prediabetes or type 2 diabetes mellitus), hypertension, dyslipidaemia or obstructive sleep apnoea.

Treatment with Saxenda® should be discontinued after 12 weeks on the 3.0 mg/day dose if patients have not lost at least 5% of their initial body weight.

As stated in the protocol and amendments (included in Appendix 16.1.1), the objectives of this full study were as follows:

Primary objective(s):

To assess the use of Saxenda® according to the approved indication (Italy only):

Secondary objective(s):

1. To assess the use of Victoza® for weight management (Italy and Germany).
2. To assess the use of Saxenda® according to the approved posology (Italy only).

Endpoints:

Primary endpoint:

The following endpoints addressed the primary objective (concerning Saxenda® in Italy only):

BMI and comorbidities were assessed according to:

- Number of patients with BMI≥30 kg/m^2 (measured less than 6 months before date of first prescription).
- Number of patients with 27 kg/m^2≤BMI<30 kg/m^2 (measured less than 6 months before date of first prescription) and
  - ≥1 relevant comorbidity registered:
    - Dysglycaemia (T2DM or prediabetes), hypertension, dyslipidaemia, obstructive sleep apnoea and/or other weight-related comorbidities.
  - No relevant comorbidities (described above) registered.
- Number of patients with BMI<27 kg/m^2 (measured less than 6 months before date of first prescription).
- Number of patients with BMI not measured within 6 months before date of first prescription.

Stopping rule was assessed according to:

- Number of patients with at least 5% weight loss (measured 16-24 weeks after first prescription date) and continuing treatment.
- Number of patients with less than 5% weight loss (measured 16-24 weeks after first prescription date) and continuing treatment.
- Mean weight loss (measured 16-24 weeks after first prescription date) in patients not treated according to stopping rule.

Secondary endpoint:

The following endpoint was used to address the first secondary objective (concerning Victoza® in Italy and Germany):

- Number of patients with Victoza® prescriptions fulfilling at least one of the following criteria:
  1. Dose information ≥3.0 mg per day, or
  2. Indication of weight management, and type 2 diabetes not part of indication.

The following endpoints were used to address the second secondary objective (concerning Saxenda® in Italy only):

- Adherence to dose escalation according to label:
  - Number of patients who have reached a dose of 3.0 mg by 12 weeks after first prescription date.
- Concomitant medication with other GLP-1 receptor agonists:
  - Number of Saxenda® patients with other GLP-1 receptor agonists prescribed during continued treatment with Saxenda®.
- Duration of treatment with Saxenda®:
  - Number of patients with a treatment duration of:
    - 0-6, 7-12, 13-18, or 19-24 months, or ongoing (current patients), with continued treatment defined as no gaps between prescriptions of more than 90 days.

8 Amendments and updates

Table 8-1 Amendments to the protocol

Number	Date	Section of study protocol	Amendment or update	Reason
1	13 June 2017	Header, PASS information, section 3.7, section 4, section 8.2.1, section 8.5.	Change the sample size of Saxenda® patients in Germany in the pilot study from 25 to at least 5 patients. Editorial changes.	Low recruitment of Saxenda® patients in Germany for pilot study.
2 (Not approved by PRAC and therefore not implemented. Replaced by amendment 3 below).	20 November 2017	Header, PASS information, sections 1, 2, 3.3-3.7, 4, 7.3, 8.1.1, 8.1.3, 8.2, 8.3, 8.4, 8.5, 8.7, 8.9, 9.1, 10, Annex 2	Run full study in Italy only. Replace target dose with final dose. Remove repeat prescription dates. Add other weight-related comorbidities. Editorial changes and clarifications.	In Germany, it was challenging to identify a sufficient number of patients on Saxenda® due to low market penetration and reluctance of sites to participate. Target dose was not well understood. Other comorbidities are part of the indication for Saxenda® but were not fully aligned in the protocol wording.
3	6 July 2018	Header, title page, PASS information, sections 1, 2, 3.1-3.7, 4, 5, 7.1, 7.2, 7.3, 8.1-8.7, 8.9, 9.1, 10, 11, Annex 2	Include only Victoza® patients for Germany and both Saxenda® and Victoza® patients for Italy in the full study. Postpone start of data collection and therefore final study report for three months. Replace target dose with final dose. Remove repeat prescription dates. Add other weight-related comorbidities. Editorial changes and clarifications.	In Germany, it was challenging to identify a sufficient number of patients on Saxenda® due to low market penetration and reluctance of sites to participate. To allow for approval of the amendment, finalisation of the full study was extended by three months. Target dose was not well understood. Other comorbidities are part of the

Number	Date	Section of study protocol	Amendment or update	Reason
				indication for Saxenda® but were not fully aligned in the protocol wording.

9 Research methods

In this document physician refers to the individual overall responsible for the conduct of the non-interventional study at a study site.

9.1 Study design

9.1.1 Type of study

This DUS was a non-interventional, multi-centre Post Authorisation Safety Study (PASS) to investigate the use of Saxenda® and Victoza® in clinical practice in patients who had initiated treatment in the Saxenda® post-marketing period. The DUS involved retrospective review of patients' medical records in two selected European Union (EU) countries 24 months after launch of Saxenda®. Physician sampling was built using intelligence databases, in order to obtain a representative sample of Saxenda®/Victoza® prescriptions according to geography. This data source was complementary to the full study and was obtained during the study period. It provided, on a national level for the two targeted countries, the distribution of sites and physicians' specialty. It did not identify individual physicians, but rather guided the site selection for the study performed by [redacted] Therefore, intelligence databases were used a priori to refine the sampling strategy (using regional distribution of physicians), and *a posteriori* to assess the representativeness of physicians in this full study.

A case report form (CRF), including all the desired data elements, was available to the selected sites; one CRF was completed per patient prescribed Saxenda® or Victoza®. The CRF was completed by the principal investigator or a study coordinator who received data abstraction training during the site initiation visit. The data was entered pseudonymised into the CRFs.

The index date, defined as the start date of data abstraction, was 24 months after launch of Saxenda® for this full study (see Figure 9-1 for an overview of the study design in the pilot study, and Figure 9-2 for an overview of the study design in the full study). The data was collected only after informed consent was obtained from the patients. All study physicians within a country were assigned the same index date and were not contacted prior to it. At or after the index date, physicians commenced selecting patient records meeting study selection criteria. Data on drug utilisation was censored on the index date.

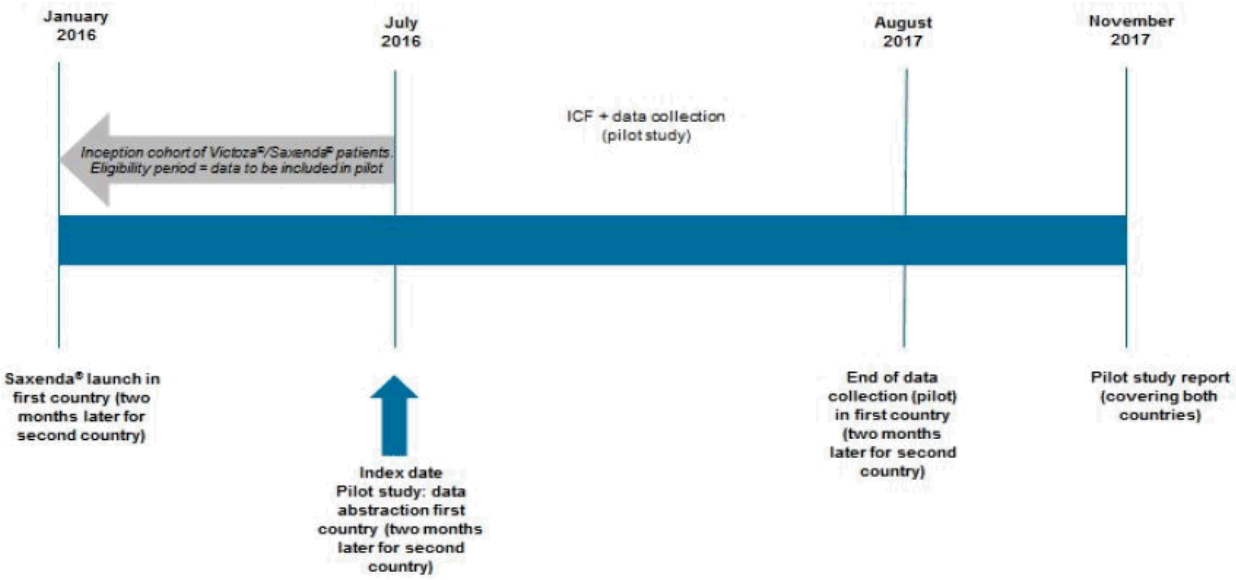


Figure 9-1 DUS overview – pilot study

Notes: The index date for the pilot study was 6 months after the launch of Saxenda®; data on drug utilisation was collected on patients from their start date of Saxenda®/Victoza® until the index date for the full study.
ICF: Informed Consent Form; DUS: drug utilisation study

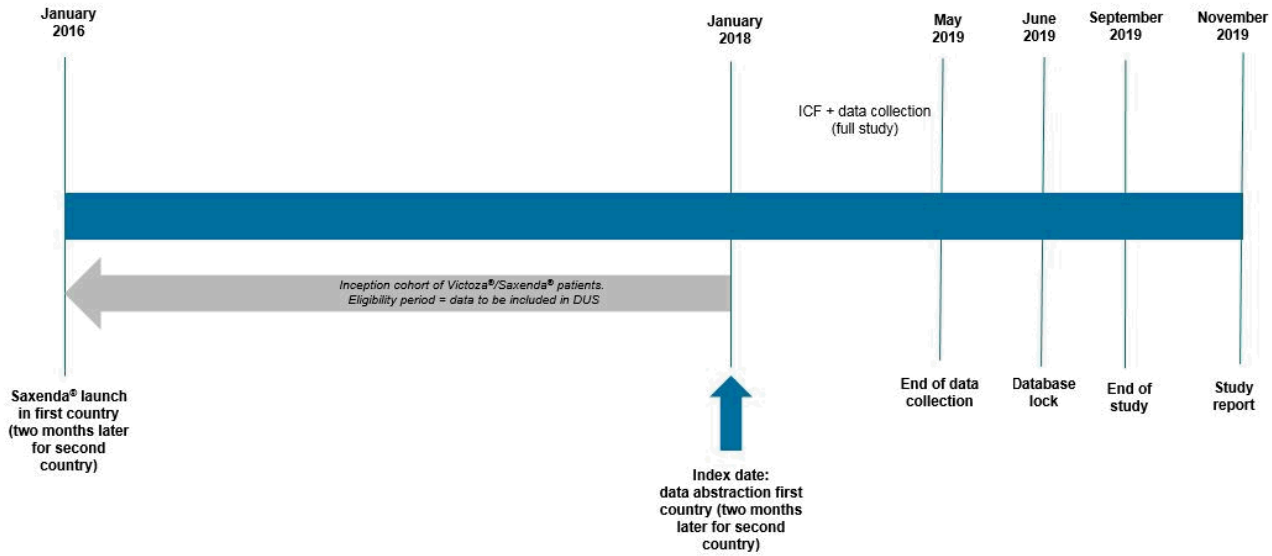


Figure 9-2 DUS overview – full study

Notes: The index date for the full study was 24 months after the launch of Saxenda®; data on drug utilisation was collected on patients from their start date of Saxenda®/Victoza® until the index date for the full study.
ICF: Informed Consent Form; DUS: drug utilisation study

9.1.2 Rationale for study design

Being retrospective in design, this study involved no intervention, and so did not impact usual medical care or affect the treatment of patients. Thus, the study reflected real-world medical practice without the potential for physician response bias which may occur in prospective studies (i.e., the Hawthorne Effect [3]). This full study did not use the same sites and patients as the pilot study, in order to reduce potential bias, e.g., physician response bias, which might have been associated with awareness of study objectives following the pilot study. Furthermore, data collection was initiated following the study-defined abstraction index date. Initiation of selection of patient records meeting study selection criteria, commenced on or following this date. Data on drug utilisation was censored from then on, and not considered in the analyses. This approach ensured that study procedures did not influence prescribing practices.

9.1.3 Treatment of patients

Patients were treated with commercially available Saxenda® or Victoza® according to routine clinical practice at the discretion of the treating physician. Saxenda® and Victoza® both contain the active substance liraglutide - a long-acting GLP-1 analogue and are both administered subcutaneously by injection. The approved posology for Saxenda® is a starting dose of 0.6 mg daily, which should be increased to 3.0 mg daily in increments of 0.6 mg with at least one-week intervals to improve gastrointestinal tolerability. If escalation to the next dose step is not tolerated for two consecutive weeks, treatment discontinuation should be considered. For Victoza®, the approved posology is a starting dose of 0.6 mg daily, which should be increased to 1.2 mg after at least one week; based on glycaemic response, the daily dose can be increased from 1.2 mg to 1.8 mg after at least one week.

9.2 Setting

Since the purpose of this full study was to investigate real-world, in-market utilisation of liraglutide, patients were identified based on the prescription rather than on a specific diagnosis. The study targeted initiators of Saxenda® or Victoza® by identifying a representative sample of physicians prescribing Saxenda® or Victoza®.

9.3 Subjects

The number of patients planned to be enrolled in this full study was 225, distributed as follows: 75 patients prescribed Saxenda® in Italy and 150 patients prescribed Victoza® (75 in Italy and 75 in Germany).

9.3.1 Inclusion criteria

To be eligible for this full study, patients were required to meet both of the following inclusion criteria:

Germany:

1. Initiation of Victoza® during the period from the launch date of Saxenda® until index date (initiation was defined as no prescription of the same brand within the previous 12 months).

Italy:

1. Initiation of Saxenda® and/or Victoza® during the period from the launch date of Saxenda® until index date (initiation was defined as no prescription of the same brand within the previous 12 months).

Note: For Italy, the first drug initiated during the index period determined the cohort (Saxenda® or Victoza® initiators).

Germany and Italy:

1. Written informed consent obtained before any study-related activities. Study-related activities (e.g., data collection) are any procedures that are carried out as part of the study, including activities to determine suitability of the study and data review and abstraction.

9.3.2 Exclusion criteria

1. Patients or physicians who previously participated in interventional programs for Saxenda® or Victoza® were not eligible to participate in the study.
2. Physicians and patients included in the pilot study were excluded from the full study.

9.3.3 Removal of patients from therapy or assessment

The patient could withdraw at will at any time.

9.3.4 Sources of patients

Patients were recruited either on-site during a visit or remotely. Informed consent from all study participants was required.

In obtaining and documenting informed consent, physicians complied with the applicable regulatory requirements and adhered to the requirements in the Declaration of Helsinki 64th World Medical Association (WMA) General Assembly (4).

Prior to any study-related activity, the physicians gave patients both oral and written information about the study in a form that the patient could read and understand.

A voluntary, signed and personally dated, informed consent form was obtained from patients prior to any study-related activity. Consent was obtained either on-site during a visit or remotely. In the latter case, the physician sent two copies of the informed consent form (ICF) to the patient who signed both copies, keeping one and sending back the other in a pre-stamped envelope to the physician.

The task of seeking informed consent was performed by the physician or another medically qualified person delegated by the physician, if permitted by local regulation, who signed and dated the patient information/ICF.

9.3.5 Methods of selection of patients

The selection of participating sites as well as the inclusion and exclusion criteria applied in this DUS allowed for inclusion of a study population as broad as possible. Furthermore, the sampling strategy was built to obtain a representative sample of physicians. Physicians were recruited according to setting characteristics, e.g., size of practice (small, medium, large), location (urban, rural), and type (academic, non-academic). In addition, patients and physicians who participated in interventional programs for Saxenda® or Victoza® were not eligible to participate in this study. The selected physicians approached eligible patients and stopped recruitment when the number of patients targeted for the site was reached. By applying this approach, the representativeness and comprehensiveness of the sample in terms of types of physicians and study population ensured generalisability of study results to the broad population of patients being prescribed Saxenda® or Victoza® in clinical practice. Furthermore, the exclusion criteria limited potential bias related to awareness of the study objectives and to extended knowledge on prescription of and use of Saxenda® and/or Victoza® (i.e., knowledge that goes beyond that obtained through normal clinical practice).

9.4 Variables

All the variables listed below were collected for Italian patients. For Germany, only the Victoza®-related variables were collected.

Site characteristics:

To evaluate the representativeness of sites the following information was collected for each participating site using a site questionnaire:

- Geographic location of physician site
- Specialty of participating physician (e.g., GPs, cardiologists, endocrinologists [or other diabetes and obesity specialists])
- Practice type (e.g., community hospital, academic/medical centre, office-based)
- Practice size (number of physicians who practice at site)

- Patient volume (i.e., number of patients and estimated number of patients prescribed Saxenda® or Victoza® during the period from the launch date of Saxenda® until index date).

Additionally, the number of sites invited to participate within each specialty was collected along with reason for refusal in order to evaluate the response rate and representativeness of the specialty. The main study site per country was disclosed via facility name, city and country on the study registration. Other sites and physicians were not identifiable in the study report.

Patient demographics, medical history, and other characteristics:

- Date of birth
- Sex
- Body weight (latest recording within 6 months before date of first prescription of Saxenda®), height, BMI (calculated), and date of anthropometric measurements (for Saxenda® patients only).

Drug utilisation:

Saxenda® or Victoza® patients:

- Brand name
- Indication prescribed at treatment initiation
- Dose throughout the treatment period

Saxenda® patients only:

- Treatment start date and end date
- Comorbidities:
  - Dysglycaemia (T2DM or prediabetes), hypertension, dyslipidaemia, obstructive sleep apnoea, and/or other weight-related comorbidities before first prescription date.
- Treatment with Victoza® prior to initiation and last dose before switching to Saxenda®
- Concomitant medication with other GLP-1 receptor agonists (brand name and start date).
- Body weight throughout the treatment period. If body weight was not available within this interval, the earliest subsequent body weight and date of measurement within the index period was recorded.

Prescription outside label

Prescription outside label was categorised as follows:

Saxenda® patients:

- BMI<27 kg/m^2 before date of first prescription
- 27 kg/m^2≤BMI<30 kg/m^2 before date of first prescription and no relevant weight-related comorbidities registered (dysglycaemia [T2DM or prediabetes], hypertension, dyslipidaemia, obstructive sleep apnoea and/or other weight-related comorbidities)
- Anthropometrics not measured before date of first prescription (i.e. BMI cannot be calculated)
- Non-adherence to dose escalation according to SmPC (i.e., daily dose of 3.0 mg not reached by 12 weeks post initiation of treatment)
- Non-adherence to stopping rule (i.e., less than 5% weight loss after 16-24 weeks on Saxenda® 3.0 mg and still on continued treatment)
- Concomitant medication with other GLP-1 receptor agonists

Victoza® patients:

- Dose ≥3.0 mg per day
- Prescribed indication of weight management, and type 2 diabetes not part of the indication

9.5 Data sources and measurement

Retrospective abstraction of data from patient medical records was performed by the principal investigator or a study coordinator who received data abstraction training during the site initiation visit. Data for each patient was recorded in accordance with normal clinical practice and no additional assessments were required.

Concomitant medication with GLP-1 receptor agonists entered into the CRF was coded using the World Health Organization (WHO) Drug Reference List. All data was entered pseudonymised into the CRF. See Section 9.4 for the list of data collected; these data was collected 24 months after the launch of Saxenda® (see Figure 9-2).

The physician kept a patient enrolment log and a log of patients evaluated for, but not included in the study throughout the enrolment period. The log included information on the number of pre-screened patients to participate the study, the number of patients who accepted, the number of patients confirmed eligible, the number and reason patients were ineligible, and the number of patients who refused. This data allowed calculation of the participation rate. Each patient signing an informed consent form was uniquely identified in the study by a patient identification number.

9.6 Bias

Selection bias

In order to minimise selection bias, the sampling strategy that was designed for this study captured a diversity of treatment settings. In addition, sites were enrolled following the distribution of site characteristics as described in intelligence databases.

Information bias

At the physician (site) level, information bias was mitigated by the retrospective design. This study involved no intervention and treatment of patients considered eligible and their medical records at a site were completed prior to the country-specific index date. Thus, the knowledge about this study (and its conduct) did not have impact on the standard medical care and Saxenda® or Victoza® prescription practices at a site and did not affect the treatment of patients. Data collected from medical records therefore reflected real-world medical practice.

At the patient level, misclassification of drug exposure was considered. Medical records provided detailed information on prescribed and/or dispensed medications but might not have contained information on the intended duration of use (days of supply) and often did not contain information on the actual use of the medications by the patient. Thus, patients might have been classified as exposed to a drug although they actually had not taken the drug. Clinical research associates (CRAs) followed up with physicians to control the quality of the abstracted information.

Missing Data

In this study, the degree of data completeness depends on the availability and quality of the data in the patient medical records as well as the completion of the data abstraction. Measures to ensure the completion of the CRF were conducted in a systematic and unbiased manner, including:

- CRF completion guidelines provided thorough instructions on completion of the CRF.
- All individuals performing data abstraction from medical records were trained on appropriate data abstraction techniques in order to minimise possible discrepancies between interpretation of the information recorded by the physician in the medical records and the individual performing the review and abstraction of the data.
- Missing data was followed up on during remote monitoring contacts.

9.7 Study size

This was a descriptive study designed to examine in-market utilisation of Saxenda®/Victoza® and thus no hypothesis testing was planned, and power calculations were not applicable. 225 patients were enrolled for this full study.

Note: When taking into account both the pilot and this full study, the total number of enrolled patients was 316 (91 patients from the pilot + 225 patients for the full study).

9.8 Data transformation

A data management plan (DMP) was created and described all functions, processes, and specifications for data collection, cleaning and validation for the DUS. High data quality standards were maintained, and processes and procedures utilised to repeatedly ensure that the data was as clean and accurate as possible when presented for analysis. Data quality was enhanced through a series of programmed data quality checks that automatically detected out-of-range or anomalous data at the time of data entry.

Data management was the responsibility of [redacted] Data Management and the identity of patients was protected in all presentations and publications as required by local/regional/national requirements. In both countries Italy and Germany and throughout the course of the study, all information collected on patients' records were identified by a study patient number. Personal identifiable data of patients was not extracted from medical records at the exception of patient's year of birth and gender.

All data captured at sites was collected and entered at the site directly into the CRFs by the principal investigator or a study coordinator who received data abstraction training during the site initiation visit. Each site only had access to the patient data entered by the individual site. Appropriate measures such as encryption of data files were used to assure confidentiality of patient data when it was transmitted over open networks.

9.8.1 Case report forms and rules for completing

All participating sites had access to the data entered for patients enrolled at their site. All site staff were fully trained in CRF completion. The principal investigator and the study coordinator who received data abstraction training during the site initiation visit were responsible for entering extracted patient data into a secure web-based electronic data capture (EDC) database via CRFs. All CRFs were completed by designated, trained personnel or the study coordinator or external data abstractor, as appropriate. The CRFs were reviewed, signed, and dated by the site physician (or designee).

The source documents were contained in the patient's medical record and data collected in the CRFs matched the data in the medical records. All original source documentation was expected to be stored at the site for the longest possible time required by local applicable regulations. The site was instructed to notify the sponsor before any destruction of medical records of study participants.

By signing the affirmation statement electronically, the physician confirmed that the information was complete and correct.

9.8.2 Corrections to CRFs

CRF data could be corrected only by the principal investigator or the study coordinator who received data abstraction training during the site initiation visit. An audit trail was maintained. If corrections were made by the physician's authorised staff after the date of the physician's signature on the affirmation statement, the statement was signed again by the physician.

9.8.3 CRF flow

When data was entered, it was available to [redacted] for data verification activities and these activities were shared with Novo Nordisk. When the final non-interventional study report is available, the data is archived by Novo Nordisk.

9.9 Statistical methods

9.9.1 Main summary measures

All data analyses were performed by [redacted]

As this was a descriptive study that investigated in-market utilisation of liraglutide, no formal statistical testing was conducted.

Characteristics of study participants were reported as mean, standard deviation (SD), median, first and third quartiles (Q1, Q3) and range for continuous variables and as number and proportion of patients with observed (non-missing) data for categorical variables. Study participation was presented, including number of sites approached for the study and response rate, by specialty, and number of patients approached, response rates, and reasons for refusal. Characteristics of the participating sites and patients were presented, stratified by country for Victoza® cohort only. The data was also evaluated and presented for other meaningful subgroups of patients (e.g., by sex or age). Participating physicians were put in perspective of non-participants i.e., specialties and geographic location of participating and non-participating physicians were described separately.

9.9.2 Main statistical methods

The full analysis set (FAS), including all recruited patients, was analysed in the study.

Details of the data analyses, along with table, listing and figure (TLF) templates, were fully described in a Statistical Analysis Plan (SAP).

For Germany, only the Victoza®-related analyses were performed.

In brief, the descriptive analyses presented Saxenda® and Victoza® utilisation by indication. Results were evaluated by site characteristics, including country and geographic region within country, to ascertain any patterns of prescribing by specific indication. The main analysis was to estimate the proportion of prescriptions outside label among Saxenda® or Victoza® patients during the entire

study period in the countries of interest. The proportion of each of the forms of prescription outside label was described (see Section 9.4). Characteristics of patients prescribed Saxenda® or Victoza® according to the respective approved SmPCs were also evaluated.

Analyses on the following were conducted:

Site characteristics

Descriptive statistics were provided for the following variables:

- Geographic location of physician site (number and proportion)
- Specialty or area of primary practice (e.g., GPs, cardiologists, endocrinologists (or other diabetes and obesity specialists), etc.) (number and proportion)
- Practice type (e.g., community hospital, academic/medical centre, office-based, etc.) (number and proportion)
- Number of physicians who practiced at site (mean, SD, median, first and third quartiles and range)
- Patient volume (i.e., number of patients and estimated number of patients using Victoza® or Saxenda®) (mean, SD, median, first and third quartiles and range)

Patient demographics, medical history, and other characteristics:

Descriptive statistics were provided for the following variables:

- Age (mean and SD; number and proportion for age categories)
- Sex (number and proportion)

Drug utilisation:

Descriptive statistics were provided for the following variables:

Saxenda® or Victoza® patients:

- Brand name (number and proportion)
- Indication prescribed at treatment initiation (number and proportion)
- Final dose reached (number and proportion for final dose categories)

Saxenda® patients only:

- Comorbidities:

- Dysglycaemia (T2DM or prediabetes), hypertension, dyslipidaemia, obstructive sleep apnoea and/or other weight-related comorbidities (number and proportion)
- Dose at 4-12 weeks and 16-24 weeks post initiation of treatment (mean, SD)
- Duration of treatment (or ongoing treatment) (mean, SD, median, first and third quartiles [Q1, Q3] and range; number and proportion for treatment completion: completed treatment or ongoing treatment)

Victoza® patients only:

- Increase in Victoza® dose to ≥3.0 mg/day (number and proportion)
- Prescription of Victoza® for weight management when type 2 diabetes is not part of the indication (number and proportion)

Prescription outside label:

Descriptive statistics for the following:

Saxenda® patients:

- BMI<27 kg/m^2 (number and proportion)
- 27 kg/m^2≤BMI<30 kg/m^2 and no relevant weight-related comorbidities registered (dysglycaemia (T2DM or prediabetes), hypertension, dyslipidaemia, obstructive sleep apnoea and/or other weight-related comorbidities) (number and proportion)
- BMI not measured within 6 months before date of first prescription (number and proportion)
- Non-adherence to dose escalation according to label (i.e., 3.0 mg not reached by 12 weeks after date of first prescription) (number and proportion)
- Non-adherence to stopping rule (i.e., less than 5% weight loss after 16-24 weeks on Saxenda® 3.0 mg and still on continued treatment) (number and proportion)
- Concomitant medication with other GLP-1 receptor agonists (brand name) (number and proportion)

Victoza® patients:

- Dose information ≥3.0 mg per day (number and proportion)
- Prescribed indication of weight management, and type 2 diabetes not part of the indication (number and proportion)

All analyses were performed using SAS 9.2 (or higher) statistical software ([redacted]). Programs, logs, and output were reviewed for accuracy according to relevant standard operating procedures (SOPs).

9.9.3 Missing values

Missing data was not imputed, and the data was analysed as they were recorded in the study CRFs.

9.9.4 Sensitivity analyses

Not applicable.

9.9.5 Amendments to the statistical analysis plan

Not applicable.

9.10 Quality control

This study was outsourced to [redacted] in accordance with Novo Nordisk SOPs. The study was performed by [redacted] with guidance, input, review and approval of Novo Nordisk, including the development of materials, recruitment, training and management of sites, site monitoring, EDC and data management and analysis.

9.10.1 Monitoring procedures

During the site initiation visit, the monitor provided training on the conduct of the study to the physician, and all site staff involved in the study. To ensure the integrity of the data, sites were monitored by a trained monitor. A risk-based monitoring approach was conducted during the study involving remote data monitoring and ad hoc on-site monitoring that were performed to examine compliance with the protocol and adherence to the data collection procedures, to assess the accuracy and completeness of submitted data, and to verify that records and documents were being properly maintained for the duration of the study. The monitor performed source data verification by review of original patient records. The physician allowed the monitor to have direct access to appropriate parts of patients' medical records relating to their participation in this study, for the purpose of verifying the data submitted by the site.

The monitor closed out each site after the last patient's data collection was completed, all data had been entered in the CRF and all outstanding monitoring issues had been resolved or addressed.

Representatives of Novo Nordisk and Competent Authorities permitted to audit/inspect all study-related documents and other materials at the site, including the Investigator Site File, the completed CRFs and the patients' original medical records. No audits / inspections occurred during the study.

9.10.2 Critical documents

Before the physician started the study (i.e., obtained informed consent from the first patient), the following documents were available at Novo Nordisk:

- Regulatory approval and/or notification as required
- Documentation of the physician's qualifications as medically qualified (for instance a short curriculum vitae [CV] or authorisation), in addition to qualification documentation of other site staff involved in study conduct
- Signed and dated agreement on the final protocol
- Approval/favourable opinion from IEC (or other appropriate bodies if required locally) clearly identifying the documents reviewed: the protocol, any amendments, patient information/ICF and any other written information to be provided to the patient, patient enrolment procedures
- Copy of IEC approved patient information/ICF/any other written information/advertisement
- Non-interventional study agreement.

9.10.3 Retention of study documentation

Novo Nordisk complies with all the requirements of Good Pharmacoepidemiological Practice (GPP) and relevant national legislation related to archiving of study documentation. Records containing patient sensitive data are not archived by Novo Nordisk but are kept with physician and patient and according to local regulations pertaining to personal data protection.

The physician agreed to archive the documentation pertaining to the study in an archive after completion or discontinuation of the study, if not otherwise notified. The physician does destroy any documents without prior permission from Novo Nordisk.

Novo Nordisk retains the documentation pertaining to the study according to company procedure and in accordance with national regulations if they require a longer retention period.

10 Results

10.1 Participants

The characteristics of the participating and non-participating sites as well as the distribution of the prescriptions when available from intelligence databases for Saxenda® and Victoza® in Italy and Germany are summarised in Table 10-1, Table 10-2, Table 10-3 and in Table 10-4.

Table 10-1 Characteristics of the German participating and non-participating sites and distribution of the German Victoza® prescriptions in intelligence databases

	Participating sites prescribing Victoza®	Non-participating Victoza® sites	Victoza® prescriptions in intelligence databases (see Appendix 16.4)
Geographical location of physician site, n(%)			[redacted]
N	16	222	488,953
North Rhine- Westphalia	4 (25.0)	29 (13.1)	108,297 (22.1)
Saxony	2 (12.5)	0 (0.0)	41,592 (8.5)
Bavaria	1 (6.3)	0 (0.0)	63,085 (12.9)
Berlin	1 (6.3)	9 (4.1)	22,273 (4.6)
Brandenburg	1 (6.3)	4 (1.8)	26,126 (5.3)
Hesse	1 (6.3)	3 (1.4)	30,247 (6.2)
Lower Saxony	1 (6.3)	0 (0.0)	35,314 (7.2)
Rhineland-Palatinate	1 (6.3)	30 (13.5)	20,658 (4.2)
Saxony-Anhalt	1 (6.3)	9 (4.1)	22,224 (4.5)
Schleswig-Holstein	1 (6.3)	3 (1.4)	13,771 (2.8)
Baden-Württemberg	0 (0.0)	17 (7.7)	47,837 (9.8)
Bremen	0 (0.0)	0 (0.0)	1,581 (0.3)
Hamburg	0 (0.0)	0 (0.0)	8,690 (1.8)
Mecklenburg-Vorpommern	0 (0.0)	20 (9.0)	20,618 (4.2)
Saarland	0 (0.0)	3 (1.4)	4,854 (1.0)
Thuringia	0 (0.0)	34 (15.3)	21,786 (4.5)
Missing	0 (0.0)	2 (0.9)	0 (0.0)
Physician's specialty, n(%)			**Analytic Platform[1]**
N	16	222	488,953
Diabetes/Endocrinology/Nutrition Medicine	15 (93.7)	68 (30.6)	191,537 (39)
Cardiology	1 (6.3)	0 (0.0)	2,614 (0.5)
General practice Medicine	0 (0.0)	96 (43.2)	281,308 (57.5)
Nephrology	0 (0.0)	0 (0.0)	6,306 (1)
Gastroenterology/Hepatology	0 (0.0)	1 (0.5)	Not evaluated
Internal Medicine	0 (0.0)	38 (17.1)	Not evaluated
Respiratory	0 (0.0)	1 (0.5)	Not evaluated
Others	0 (0.0)	0 (0.0)	6,203 (1)

	Participating sites prescribing Victoza®	Non-participating Victoza® sites	Victoza® prescriptions in intelligence databases (see Appendix 16.4)
Missing	0 (0.0)	1 (0.5)	Not evaluated

[1] Data collected for the period from July 2016 to April 2018
Reference EOT: Table 14-1 and Table 14-2

A total of 16 sites participated in the DUS in Germany. The most common geographic locations of the participating sites were the federal states of North Rhine-Westphalia (25.0%) and Saxony (12.5%) whereas the distribution of the 222 sites that did not participate in the study was different. Nonetheless, according to the intelligence database [redacted] that collected prescription data within the period from July 2016 to April 2018, Victoza® was mainly prescribed in North Rhine-Westphalia (22.1%), Bavaria (12.9%), Baden-Württemberg (9.8%) and Saxony (8.5%). Therefore, prescriptions are geographically distributed in a similar way as the participating sites, although only one participating site (6.3%) was located in Bavaria, suggesting that this federal state might be underrepresented.

Among participating sites, the most common physician's specialty was Diabetology/Endocrinology/Nutrition Medicine (93.7%), followed by Cardiology (6.3%) whereas General practitioners represented 43.2% of the non-participating sites, followed by physicians in Diabetology/Endocrinology/Nutrition Medicine (30.6%%) and internists (17.1%). Based on the intelligence database Analytic platform that collected prescription data within the period from July 2016 to April 2018, 57.5% of Victoza® prescriptions are issued by General practitioners and 39.4% by physicians in Diabetology/Endocrinology/Nutrition Medicine. Although some specialties might be underestimated by the Analytic platform because it does not cover physicians from secondary care (see Appendix 16.4), the distribution of prescriptions suggests that General practitioners were underrepresented within the participating sites.

Table 10-2 Characteristics of the German participating sites prescribing Victoza®

Participating sites prescribing Victoza®	
Rural vs urban location of physician site, n(%)[1]	
Total number of sites	16
Urban	10 (62.5)
Rural	6 (37.5)
Practice type, n(%)	
Total number of sites	16
Public hospital	0 (0.0)
Private hospital	0 (0.0)
Academic centre	0 (0.0)
Medical centre	12 (75.0)
Office-based	4 (25.0)

Participating sites prescribing Victoza®	
Other	0 (0.0)
Missing	0 (0.0)
Practice size (number of physicians per site)	
Total number of physicians	79
Mean (SD)	4.9 (9.04)
Median	2
Min, Max	1, 38
Q1, Q3	1, 4
Missing	0
1	5 (31.3)
2-5	8 (50.0)
>=6	3 (18.8)
Number of patients prescribed Victoza® per site	
Total number of patients	1220
Mean (SD)	76.3 (63.37)
Median	53
Min, Max	4, 200
Q1, Q3	29, 115
Missing	0
0	0
1-10	2 (12.5)
11-25	2 (12.5)
26-50	4 (25.0)
>=50	8 (50.0)

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value
[1] Participating sites were categorized as being rural or urban based on their geographic location after applying definition developed and previously used by Göddecke-Stellmann J et al, 2011 (5). This method consists in categorizing geographical locations listed as "metropolitan" as "urban"; all locations not listed as "metropolitan" were categorized as "rural".
Reference EOT: Table 14-1

Ten participating sites (62.5%) were located in urban areas after applying the criteria from Göddecke-Stellmann J et al, 2011 (5) to define urban areas.

Medical centre was the most common practice type (75%), followed by office-based practice (25%). Across sites, the mean (±SD) of practice size was 4.9 (±9.0) physicians and the mean (±SD) number patients prescribed Victoza® was 76.3 (±63.4).

Table 10-3 Characteristics of the Italian participating sites prescribing Victoza® or Saxenda® and non-participating sites and distribution of the Italian Victoza® and Saxenda® prescriptions in intelligence databases

	Participating sites prescribing Victoza® or Saxenda®	Non-participating sites prescribing Victoza® or Saxenda®	Victoza® prescriptions in intelligence databases (see Appendix 16.4)	Saxenda® prescriptions in intelligence databases (see Appendix 16.4)
Geographical location of physician site, n(%)			[redacted]	
N	25	156	922,056	39,217
Lazio	6 (24.0)	8 (5.1)	101,804 (11.0)	9,096 (23.2)
Lombardy	5 (20.0)	30 (19.2)	178,345 (19.3)	10,120 (25.8)
Campagna	3 (12.0)	15 (9.6)	96,679 (10.5)	2,081 (5.3)
Liguria	2 (8.0)	6 (3.8)	13,092 (1.4)	1,734 (4.4)
Piedmont	2 (8.0)	11 (7.1)	67,600 (7.3)	3,422 (8.7)
Sicily	2 (8.0)	19 (12.2)	96,302 (10.4)	3,522 (9.0)
Tuscany	2 (8.0)	9 (5.8)	57,495 (6.2)	2,482 (6.3)
Emilia Romagna	1 (4.0)	7 (4.5)	13,360 (1.4)	949 (2.4)
Sardinia	1 (4.0)	7 (4.5)	34,993 (3.8)	258 (0.7)
Veneto	1 (4.0)	11 (7.1)	64,823 (7.0)	1,724 (4.4)
Abruzzo	0 (0.0)	5 (3.2)	894 (0.1)	252 (0.6)
Aosta Valley	0 (0.0)	0 (0.0)	816 (0.1)	65 (0.2)
Apulia	0 (0.0)	12 (7.7)	81,858 (8.9)	2,046 (5.2)
Basilicata	0 (0.0)	3 (1.9)	6,239 (0.7)	172 (0.4)
Calabria	0 (0.0)	6 (3.8)	40,286 (4.4)	418 (1.1)
Friuli- Venezia Giulia	0 (0.0)	1 (0.6)	20,687 (2.2)	192 (0.5)
Marche	0 (0.0)	1 (0.6)	20,155 (2.2)	460 (1.2)
Molise	0 (0.0)	2 (1.3)	4,575 (0.5)	88 (0.2)
Trentino- South Tirol	0 (0.0)	2 (1.3)	8,444 (0.9)	53 (0.1)
Umbria	0 (0.0)	1 (0.6)	13,609(1.5)	83 (0.2)
Physician's specialty, n(%)			[redacted]	
N	25	156	~ 685,000	~ 4,000
Diabetes/Endocrinology/Obesity/Human Nutrition	24 (96.0)	124 (79.5)	~ 205,500 (29.0)	~ 2,000 (50.0)
Gastroenterology/Hepatology	1 (4.0)	1 (0.6)	~ 0 (0.0)	~ 0 (0.0)
General practice Medicine	0 (0.0)	3 (1.9)	~ 465,800 (68.0)	~ 1,000 (25.0)
Cardiology	0 (0.0)	10 (6.4)	~ 13,700 (2.0)	~ 1,000 (25.0)
Internal Medicine	0 (0.0)	13 (8.3)	Not evaluated	Not evaluated
Nephrology	0 (0.0)	2 (1.3)	Not evaluated	Not evaluated
Neurology	0 (0.0)	1 (0.6)	Not evaluated	Not evaluated
Ophthalmology	0 (0.0)	1 (0.6)	Not evaluated	Not evaluated
Other	0 (0.0)	1 (0.6)	Not evaluated	Not evaluated

[1] Data collected for the period from January 2016 to January 2018
[2] Data collected for the period from January 2016 to January 2017
Reference EOT: Table 14-1 and Table 14-2

In Italy a total of 25 sites participated in the recruitment of either Saxenda® or Victoza® patients. Among these sites, the most common geographic locations were Lazio (24.0%), Lombardy (20.0%) and Campagna (12.0%). Among the 156 non-participating sites, Lombardy and Campagna accounted for 19.2% and 9.6% of sites, respectively but the Lazio region represented only 5.1% of the non-participating sites. Based on the intelligence database [redacted] that collected data within the period from January 2016 to January 2018, Victoza® was mostly prescribed within the 3 most prevalent regions identified among the participating sites with the following proportions: 19.3% in Lombardy, 11% in Lazio and 10.5% in Campagna. With regards to Saxenda®, data from the [redacted] also reported most of the prescriptions in Lombardy (25.8%) and in Lazio (23.2%) and the third most reported region was Sicily (9%), that represented 8% of the participating sites.

Most of the participating physicians were specialised in Diabetes/Endocrinology/Obesity/Human Nutrition (96%) whereas this category represented only 79.5% of the non-participating sites and internal medicine accounted for 8.3% of the non-participating sites, followed by cardiology (6.4%). Based on the intelligence database [redacted] that collected data within the period from January 2016 to January 2017, physicians with specialty in Diabetes/Endocrinology/Obesity/Human Nutrition issued 29% of Victoza® and 50% of Saxenda® prescription volume. General practitioners prescribe 68% of Victoza® and 50% of Saxenda® volume according to the data from the [redacted]. Although, the coverage of the [redacted] is low and includes only private offices and not the hospital-specific physician specialities (see Appendix 16.4), the distribution of prescriptions suggests that specialties belonging to Diabetes/Endocrinology/Obesity/Human Nutrition were overrepresented among the participating sites.

Table 10-4 Characteristics of the Italian participating sites prescribing Victoza® or Saxenda®

Participating sites prescribing Victoza® or Saxenda®	
Rural vs urban location of physician site, n(%) [1]	
Total number of sites	25
Urban	17 (68.0)
Rural	8 (32.0)
Practice type, n(%)	
Total number of sites	25
Public hospital	18 (72.0)
Private hospital	2 (8.0)
Academic centre	4 (16.0)
Medical centre	1 (4.0)
Office-based	0 (0.0)
Other	0 (0.0)
Missing	0 (0.0)
Practice size (number of physicians per site)	

Participating sites prescribing Victoza® or Saxenda®	
Total number of physicians	202
Mean (SD)	8.1 (13.85)
Median	3
Min, Max	1, 50
Q1, Q3	2, 5
Missing	0
1	5 (20.0)
2-5	14 (56.0)
>=6	6 (24.0)
Number of patients prescribed Saxenda® per site	
Total number of patients	268
Mean (SD)	10.7 (15.40)
Median	5
Min, Max	0, 60
Q1, Q3	0, 14
Missing	0
0	9 (36.0)
1-10	9 (36.0)
11-25	3 (12.0)
26-50	3 (12.0)
>=50	1 (4.0)
Number of patients prescribed Victoza® per site	
Total number of patients	1466
Mean (SD)	58.6 (83.63)
Median	30
Min, Max	0, 280
Q1, Q3	4, 50
Missing	0
0	3 (12.0)
1-10	9 (36.0)
11-25	0
26-50	7 (28.0)
>=50	6 (24.0)

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value
[1] Participating sites were categorized as being rural or urban based on their geographic location after applying definition developed and previously used by Göddecke-Stellmann J et al, 2011 (5). This method consists in categorizing geographical locations listed as "metropolitan" as "urban"; all locations not listed as "metropolitan" were categorized as "rural".
Reference EOT: Table 14-1

Seventeen participating sites (68.0%) were located in urban areas according to the criteria developed by Göddecke-Stellmann J et al, 2011 (5).

Public hospital was the most common practice type (72%), followed by academic centres (16%) with a practice size of on average (±SD) 8.1 (±13.9) physicians per site. The mean (±SD) number of

patients prescribed Victoza® and Saxenda® were 58.6 (±83.6) and 10.7 (±15.4), respectively as shown in Table 10-4.

The patient disposition for this study is summarised in Table 10-5.

Table 10-5 Patient disposition

	Italy	Germany	Overall
Total number of patients pre-screened, n	261	179	440
Number of patients pre-screened and not enrolled, n (%) [1]	111 (42.5)	104 (58.1)	215 (48.9)
Reason for non-enrolment			
Patient Refusal	11 (9.9)	15 (14.4)	26 (12.1)
Patient did not meet inclusion criteria			
Initiation of Saxenda® or Victoza® during index period, n (%) [2]	9 (8.1)	18 (17.3)	27 (12.6)
Informed consent obtained, n (%) [2]	4 (3.6)	5 (4.8)	9 (4.2)
Patient met exclusion criterion			
Patients or physicians who previously participated in interventional programs for Saxenda® or Victoza®, n (%) [2]	0 (0.0)	0 (0.0)	0 (0.0)
Patient participated in pilot study, n (%) [2]	0 (0.0)	0 (0.0)	0 (0.0)
Not included because site reached recruitment target, n (%)	88 (79.3)	67 (64.4)	155 (72.1)
Patient not successfully contacted	3 (2.7)	2 (1.9)	5 (2.3)
Missing data on reason for non-enrolment	0 (0.0)	2 (1.9)	2 (0.9)
Number of patients enrolled in Full analysis set, n (%) [1]	150 (57.5)	75 (41.9)	225 (51.1)
Study duration for patients in Full analysis set (months) [3]			
N	149	75	224
Mean (SD)	11.03 (6.422)	12.90 (7.365)	11.66 (6.793)
Median	10.4	13	10.65
Q1, Q3	6.7, 16	7.3, 20.2	6.75, 17.55
Missing	1	0	1

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value
Index is defined as 24 months after launch of Saxenda® in the country
[1] Percentage based on total number of patients approached.
[2] Percentage based on number of patients approached and not enrolled
[3] Study follow-up duration is defined as: (Index date – Treatment initiation date + 1)/30.44
Reference EOT: Table 14-5

Overall, 48.9% patients being pre-screened were not enrolled in the study (42.5% patients in Italy and 58.1% patients in Germany). Among these, 72.1% (79.3% patients in Italy and 64.4% patients in Germany) were not included because site reached recruitment target.

The number of patients in the FAS is 225, with 150 patients in Italy and 75 patients in Germany. In FAS, the overall mean (±SD) study duration available for 224 patients was 11.7 (±6.8) months (See Table 10-5).

Table 10-6 Study duration and treatment duration for patients in full analysis set described for Victoza® and Saxenda®, separately

	Victoza® Italy N=75	Victoza® Germany N=75	Victoza® Overall N=150	Saxenda® Italy N=75
Study follow-up duration (months) [1]				
N	74	75	149	75
Mean (SD)	11.70 (6.385)	12.90 (7.365)	12.30 (6.899)	10.38 (6.434)
Median	10.9	13	11.2	9.1
Q1, Q3	7, 17.7	7.3, 20.2	7.3, 18.7	4.8, 15.8
Missing	1	0	1	0
Number of patients who withdrew from study during study period, n (%) [2]				
	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Number of patients who discontinued treatment, n (%) [2]	5 (6.7)	5 (6.7)	10 (6.7)	43 (57.3)
Duration of treatment (months) during the index period among patients who discontinued treatment [3]				
N	5	5	10	39
Mean (SD)	8.00 (6.092)	5.62 (3.114)	6.81 (4.731)	4.59 (3.095)
Median	7	5.3	6.15	4.2
Q1, Q3	4.7, 7.8	2.7, 7.9	2.7, 7.9	1.9, 6.5
Missing	0	0	0	4

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value
Index is defined as 24 months after launch of Saxenda® in the country
[1] Study follow-up duration is defined as: (Index date – Treatment initiation date + 1)/30.44
[2] Percentage based on number of patients enrolled in Victoza® Full analysis set and Saxenda® Full analysis set, separately
[3] Treatment duration is defined as (last dose of treatment date – Treatment initiation date)/30.44
Reference EOT: Table 14-5

In the Victoza® analysis set, there were 150 patients, with 75 patients each in Italy and Germany. The overall mean (±SD) study duration available for 149 patients treated with Victoza® was 12.3 (±6.9) months. None of the Victoza® patients withdrew from study during the study period. Overall, 10 (6.7%) patients discontinued Victoza® with 5 patients each in Italy and Germany. The mean (±SD) duration of treatment was 6.8 (±4.7) months for patients who discontinued treatment.

In the Saxenda® analysis set, there were 75 patients, all being from Italy by study design. The mean (±SD) study duration of these patients was 10.4 (±6.4) months. None of the Saxenda® patients withdrew from the study during the study period. A total of 43 (57.3%) patients discontinued Saxenda® and their mean (±SD) duration of treatment was 4.6 (±3.1) months (See Table 10-6).

Table 10-7 Availability of parameters in Saxenda® patients

Parameter	Italy (N=75)
Number of Saxenda® patients with available parameter	
Age	75 (100.0)
Gender	75 (100.0)
Comorbidities	75 (100.0)
Adult height [1]	74 (98.7)
Body weight in kg at first Saxenda® prescription [2]	73 (97.3)
Body Weight at 16-24 weeks of treatment	17 (22.7)
Indication prescribed	75 (100.0)
Concomitant medication containing GLP-1 receptor agonists (Brand name and start date)	75 (100.0)
Availability of parameters among patients who completed at least 12 weeks of treatment	
N	51
Current dose at 4-12 weeks [3]	29 (56.9)
Date of start dose within the period 4-12 weeks [3]	29 (56.9)
Availability of parameters among patients who completed at least 16 weeks of treatment	
N	40
Current dose at 16-24 weeks [4]	13 (32.5)
Date of start dose within the period 16-24 weeks	13 (32.5)
All of the above	3 (4.0)

GLP-1: Glucagon-Like Peptide-1.
[1] At Week 0
[2] Latest recording within six months before date of first prescription of Saxenda®
[3] Assessed 4-12 weeks after first prescription date. A total of N=51 patients had at least 12 weeks of treatment.
[4] Assessed 16-24 weeks after first prescription date. A total of N=40 patients had at least 16 weeks of treatment.
Reference EOT: Table 14-3

Overall, only 3 (4.0%) patients treated with Saxenda® had all the parameters available (see Table 10-7). Age, gender, comorbidities, indication prescribed and concomitant medication containing GLP-1 receptor agonists were the 5 parameters which were available in all patients.

Table 10-8 Availability of parameters in Victoza® patients

Parameter	Italy (N=75)	Germany (N=75)	Total (N=150)
Number of Victoza® patients with available parameter n(%)			
Age	75 (100.0)	75 (100.0)	150 (100.0)
Gender	75 (100.0)	75 (100.0)	150 (100.0)
Initial dose prescribed [1]	74 (98.7)	75 (100.0)	149 (99.3)
Indication prescribed	75 (100.0)	75 (100.0)	150 (100.0)
Dose escalation of Victoza®	74 (98.7)	75 (100.0)	150 (100.0)
All of the above	74 (98.7)	75 (100.0)	149 (99.3)

[1] At Week 0
Reference EOT: Table 14-4

Overall, 99.3% patients treated with Victoza® had all parameters available (see Table 10-8) with 98.7% patients in Italy and 100.0% patients in Germany. Age, gender and indication prescribed were the 3 parameters which were available in all patients in both, Italy and Germany.

10.2 Descriptive data

Patient demographics by country are summarised in Table 10-9.

Table 10-9 Patient demographics by country

	Victoza® Analysis Set			Saxenda® Analysis Set
	Italy (N=75)	Germany (N=75)	Overall (N=150)	Italy (N=75)
Age (years) [1]				
N	75	75	150	75
Mean (SD)	63.1 (11.98)	58.6 (11.42)	60.9 (11.88)	55.5 (12.02)
Median	66	61	62	56
Min, Max	20, 83	34, 88	20, 88	22, 78
Missing	0	0	0	0
Age categories, n (%)				
<18	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
18-29	1 (1.3)	0 (0.0)	1 (0.7)	1 (1.3)
30-39	1 (1.3)	5 (6.7)	6 (4.0)	7 (9.3)
40-49	7 (9.3)	10 (13.3)	17 (11.3)	14 (18.7)
50-59	19 (25.3)	20 (26.7)	39 (26.0)	27 (36.0)
60-64	7 (9.3)	17 (22.7)	24 (16.0)	7 (9.3)
65-69	12 (16.0)	11 (14.7)	23 (15.3)	8 (0.7)
70-74	15 (20.0)	8 (10.7)	23 (15.3)	6 (8.0)
>=75	13 (17.3)	4 (5.3)	17 (11.3)	5 (6.7)

	Victoza® Analysis Set			Saxenda® Analysis Set
	Italy (N=75)	Germany (N=75)	Overall (N=150)	Italy (N=75)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Gender				
Female	38 (50.7)	35 (46.7)	73 (48.7)	48 (64.0)
Male	37 (49.3)	40 (53.3)	77 (51.3)	27 (36.0)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value.
[1] Age is calculated as year of treatment initiation minus year of birth as reported in the CRF
Reference EOT: Table 14-7

In the Victoza® analysis set, the overall mean (±SD) patient age was 60.9 (±11.9) years. The mean (±SD) patient age was 63.1 (±11.9) years in Italy and 58.6 (±11.4) years in Germany. Overall, the highest proportion of patients (26.0%) was in the age category of 50-59 years. The proportion of male and female patients were similar (51.3% vs. 48.7%) as shown in Table 10-9. The distribution of age and gender among Victoza® patients is very similar to the corresponding distributions of age and gender of patients prescribed Victoza® observed in the intelligence database [redacted] as described in Table 10-10.

In the Saxenda® analysis set, the mean (±SD) patient age was 55.5 (±12.0) years, with a peak in the 50-59 years age category (36.0%). There was a higher proportion of female patients than male patients (64.0% vs. 36.0%) as shown in Table 10-9.

Table 10-10 Characteristics of the German Victoza® participating patients and German Victoza® prescriptions in intelligence database

	Patients	Victoza® prescriptions using [redacted] (see Appendix 16.4)	
Gender, n (%)		**Among GPs**	**Among diabetologists**
N	75		
Female	35 (46.7)	1689 (47.6)	1599 (49.1)
Male	40 (53.3)	1858 (52.4)	1660 (50.9)
Age categories, n (%)			
<18	0 (0.0)	0 (0.0)	0 (0.0)
18-29	0 (0.0)	27 (0.8)	17 (0.5)
30-39	5 (6.7)	104 (2.9)	117 (3.6)
40-49	10 (13.3)	374 (10.5)	344 (10.5)
50-59	20 (26.7)	915 (25.8)	1015 (31.1)
60-64	17 (22.7)	620 (17.5)	618 (19.0)
65-69	11 (14.7)	654 (18.4)	569 (17.4)
70-74	8 (10.7)	395 (11.1)	322 (9.9)
>=75	4 (5.3)	458 (12.9)	259 (7.9)

GP: General Practitioner.
[1] Data collected for the period from April 2016-April 2018

Saxenda® anthropometric patient characteristics at treatment initiation are summarised in Table 10-11.

Table 10-11 Saxenda® anthropometric patient characteristics at treatment initiation

	Saxenda® Analysis Set Italy (N=75)
Height (cm) [1]	
N	74
Mean (SD)	166.63 (9.785)
Median	165.0
Q1, Q3	159.0, 175.0
Missing	1
Weight (kg) [2]	
N	73
Mean (SD)	106.32 (22.445)
Median	105.0
Q1, Q3	88.0, 119.0
Missing	2

	Saxenda® Analysis Set Italy (N=75)
Body mass index (kg/m^2)	
N	73
Mean (SD)	38.17 (6.909)
Median	36.9
Q1, Q3	32.6, 42.6
Missing	2
Body mass index categories (kg/m^2)	
<18.5	0 (0.0%)
≥18.5-<25	0 (0.0%)
≥25-<27	0 (0.0%)
≥27-<30	3 (4.0%)
≥30-<40	40 (53.3%)
≥40	30 (40.0%)
Missing	2 (2.7%)

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile.
[1] At Week 0
[2] Latest recording within six months before date of first prescription of Saxenda®
Reference EOT: Table 14-8

The mean (±SD) height was 166.6 ± 9.8 cm. Patients had mean (±SD) weight of 106.3 (±22.4) kg and mean BMI of 38.2 (±6.9) kg/m^2, respectively, with a majority of patients (53.3%) having a BMI of ≥30 – <40 kg/m^2 as shown in Table 10-11.

Saxenda® patient comorbidities ongoing at treatment initiation are summarised in Table 10-12.

Table 10-12 Saxenda® patient comorbidities ongoing at treatment initiation

	Saxenda® Analysis Set Italy (N=75)
Total number of weight related comorbidities ongoing at treatment initiation, n (%)	
0	20 (26.7)
1	21 (28.0)
2	17 (22.7)
3	12 (16.0)
4	4 (5.3)
>4	1 (1.3)
Dysglycaemia, n (%) [1]	18 (24.0)
Hypertension, n (%)	31 (41.3)
Dyslipidaemia, n (%)	29 (38.7)

	Saxenda® Analysis Set Italy (N=75)
Obstructive sleep apnoea, n (%)	12 (16.0)
Other weight-related comorbidities, n (%)	19 (25.3)
Non-alcoholic fatty liver disease	6 (8.0)
GORD	4 (5.3)
Osteoarthritis/Osteoarthrosis	4 (5.3)
Vertebral column disorders	3 (4.0)
Gallbladder Disease	2 (2.7)
[redacted]	2 (2.7)
[redacted]	1 (1.3)
CAD	1 (1.3)
[redacted]	1 (1.3)
Hypothyroidism	1 (1.3)
Vitamin D Deficiency	1 (1.3)

GORD: Gastro-Oesophageal Reflux Disease. [redacted] CAD: Coronary Artery Disease.
[1] Dysglycaemia refers to type 2 diabetes or prediabetes
Reference EOT: Table 14-9

A majority of patients (73.3%) had ≥1 weight-related comorbidities ongoing at treatment initiation. Hypertension was the most commonly reported (41.3%) weight-related comorbidity followed by dyslipidaemia (38.7%) and dysglycaemia (24.0%). Sleep apnoea disorders were reported in 16.0% of patients, and other weight-related comorbidities in 25.3% of patients. Among these other weight-related comorbidities, 11 kinds of comorbidities were reported but the most prevalent ones were non-alcoholic fatty liver disease (n=6), gastro-oesophageal reflux disease (GORD) (n=4) and osteoarthritis/osteoarthrosis (n=4) as shown in Table 10-12.

In the Victoza® analysis set, overall 99.3% patients were prescribed Victoza® for T2DM with 100.0% patients in Germany and 98.7% patients in Italy. The majority of patients (83.3%) received a dose of 0.6 mg at initial prescription; however, 13.3% of patients had a starting dose of 1.2 mg. Similar trends were reported in Italy and Germany. A total of 81 (54.0%) patients reported 1 change in Victoza® dose, and 37 (24.7%) patients reported 2 changes. Only 1 (0.7%) patient was reported with at least 1 prescription with dose information of 3.0 mg/day. Overall, 62.0% patients reached a final Victoza® dose of 1.2 mg/day followed by 26.0% patients reaching a final dose of 1.8 mg/day; as shown in Table 10-13.

Table 10-13 Victoza® prescription information

	Victoza® Analysis Set		
	Italy (N=75)	Germany (N=75)	Overall (N=150)
Victoza® indication, n (%)			
T2DMs	74 (98.7)	75 (100.0)	149 (99.3)
Indication of weight management without T2DM	1 (1.3)	0 (0.0)	1 (0.7)
Victoza® dose at initial prescription, n (%)			
0.6 mg	62 (82.7)	63 (84.0)	125 (83.3)
1.2 mg	11 (14.7)	9 (12.0)	20 (13.3)
1.8 mg	1 (1.3)	1 (1.3)	2 (1.3)
Other	0 (0.0)	2 (2.7)	2 (1.3)
Number of Victoza® dose changes, n (%)			
0	10 (13.3)	14 (18.7)	24 (16.0)
1	36 (48.0)	45 (60.0)	81 (54.0)
2	25 (33.3)	12 (16.0)	37 (24.7)
>2	4 (5.3)	4 (5.3)	8 (5.3)
Number of patients with at least one prescription with dose information ≥3.0 mg/day, n (%)	1 (1.3)	0 (0.0)	1 (0.7)
Final Victoza® dose reached, n (%)			
0.6 mg/day	4 (5.3)	12 (16.0)	16 (10.7)
1.2 mg/day	44 (58.7)	49 (65.3)	93 (62.0)
1.8 mg/day	25 (33.3)	14 (18.7)	39 (26.0)
3 mg/day	1 (1.3)	0 (0.0)	1 (0.7)
Missing	1 (1.3)	0 (0.0)	1 (0.7)

Reference EOT: Table 14-23

In the Saxenda® analysis set, 94.7% patients prescribed Saxenda® had obesity. One patient switched from Victoza® 1.8 mg to Saxenda® 3.0 mg. However, this patient started Victoza® during the index period and is therefore included in the Victoza® analysis set.

The dose at initial prescription was available for all patients; the vast majority of patients (93.3%) were prescribed Saxenda® at a starting dose of 0.6 mg. For 9 (12%) patients, Saxenda® dose at 0 – 4 weeks was missing and for 46 (61.3%) patients and for 62 (82.7%) patients at 4 – 12 weeks and at 12 – 24 weeks, respectively. A total of 98.6% patients reported at least 1 change in Saxenda® dose, and the majority of patients (73.3%) underwent more than 2 changes of dose. Out of the 62 patients who, at index date, had completed at least 12 weeks of treatment or had reached 3.0 mg regardless

of the duration of treatment, 45 (72.6%) patients had reached the final dose of 3.0 mg/day, as shown in Table 10-14.

Table 10-14 Saxenda® prescription information

	Saxenda® Analysis Set Italy (N=75)
Saxenda® indication prescribed, n (%)	
BMI ≥ 30 kg/m² (obese)	71 (94.7)
≥ 27 kg/m² to < 30 kg/m² (overweight) in the presence of at least one weight-related comorbidity	3 (4.0)
Other	1 (1.3)
Victoza® to Saxenda® switch n (%) [1]	0 (0.0)
Saxenda® dose at initial prescription, n (%)	
0.6 mg	70 (93.3)
1.2 mg	2 (2.7)
1.8 mg	2 (2.7)
2.4 mg	0 (0.0)
3.0 mg	1 (1.3)
Other	0 (0.0)
Missing	0 (0.0)
Saxenda® dose at 0-4 weeks, n (%)	
0.6 mg	0 (0.0)
1.2 mg	11 (14.7)
1.8 mg	13 (17.3)
2.4 mg	7 (9.3)
3.0 mg	35 (46.7)
Other	0 (0.0)
Missing regardless discontinuation Saxenda® before week 4	9 (12.0)
Missing because discontinued Saxenda® before week 4	6 (8.0)
Saxenda® dose at 4-12 weeks, n (%)	
0.6 mg	1 (1.3)
1.2 mg	3 (4.0)
1.8 mg	5 (6.7)
2.4 mg	5 (6.7)
3.0 mg	14 (18.7)
Other	1 (1.3)
Missing regardless discontinuation Saxenda® before week 12	46 (61.3)
Missing because discontinued Saxenda® before week 12	23 (30.7)
Saxenda® dose at 12-24 weeks, n (%)	
0.6 mg	0 (0.0)
1.2 mg	0 (0.0)

	Saxenda® Analysis Set Italy (N=75)
1.8 mg	2 (2.7)
2.4 mg	3 (4.0)
3.0 mg	8 (10.7)
Other	0 (0.0)
Missing regardless discontinuation Saxenda® before week 24	62 (82.7)
Missing because discontinued Saxenda® before week 24	45 (60.0)
Number of Saxenda® dose changes, n (%)	
0	1 (1.3)
1	10 (13.3)
2	9 (12.0)
>2	55 (73.3)
Patients who, at index date, have completed at least 12 weeks of treatment or have reached 3.0mg even though they have not completed 12 weeks of treatment.	
N	62
Final Saxenda® dose of 3.0 mg/day, n (%) [3], n (%)	45 (72.6)

BMI: Body Mass Index.
[1] 1 subject (Subject ID=[redacted]) switched to a [redacted] mg Saxenda® dose from [redacted] mg Victoza® dose on [redacted]. However, since the patient started Victoza® during the Index period, it was considered in the Victoza® Analysis Set and therefore it is not displayed in the tables which considers only Saxenda® Analysis Set.
[2] Percentage calculated among patients switched from Victoza®.
[3] Total number of patients considered for the denominator (N=62) includes only patients whom, at index date, have completed at least 12 weeks of treatment or have reached 3.0 mg even though they have not completed 12 weeks of treatment. Patients which at index date have not completed 12 weeks of treatment and have not reached 3.0mg dose were excluded from this calculation.
Reference EOT: Table 14-24

10.3 Outcome data

10.3.1 Main results

10.3.1.1 Primary variable

Results on use of Saxenda® according to approved indication is presented in Table 10-15.

Table 10-15 Use of Saxenda® according to approved indication

	Saxenda® Analysis Set Italy (N=75)
BMI	
BMI ≥ 30 kg/m² [1]	70 (93.3)
BMI ≥ 27 kg/m² and BMI < 30 kg/m² [1]	3 (4.0)

	Saxenda® Analysis Set Italy (N=75)
BMI < 27 kg/m² [1]	0 (0.0)
BMI unknown (weight or height not measured) [1]	2 (2.7)
Comorbidities among patients with BMI ≥ 27 kg/m² and BMI < 30 kg/m² [1]	
≥ 1 "weight related comorbidity" reported [2,3,4]	2 (66.7)
Dysglycaemia [4]	0 (0.0)
Hypertension [4]	0 (0.0)
Dyslipidaemia [4]	0 (0.0)
Obstructive sleep apnoea [4]	0 (0.0)
Other "weight-related comorbidities" [4,5]	2 (66.7)
No "weight related comorbidity" reported [2,3]	1 (33.3)
Completed at least 16 weeks of treatment before index date	40 (53.3)
Adherence to the stopping rules in patient with at least 16 weeks of treatment [6]	
N	40
Patients adherent to the stopping rule: At least 5% weight loss and continuing treatment [7]	11 (27.5)
Less than 5% weight loss and continuing treatment [7]	2 (5.0)
Body measurements not taken between week 16 to 24	23 (57.5)
Patients stopping treatment	4 (10.0)
Mean weight loss (%) based on the last weight measurement observed within the index period [8] in patients not treated according to stopping rule	
N	2
Mean (SD)	-5.65 (4.738)
Median	-5.6
Q1,Q3	-9.0, -2.3
Missing	0
Number of patients having at least 12 weeks of treatment	51 (68.0)
N	
Adherence to treatment recommendations in patients with at least 12 weeks of treatment [9]	
N	51
Number of non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date) [9]	19 (37.3)
Number of adherent patients (3.0 mg reached by 12 weeks after first prescription date) [9]	32 (62.7)
Number of patients with more than 5% weight loss at 4-12 weeks of treatment, n (%) [10]	17 (33.3)
Body measurements not taken between week 4 to 12 [9]	19 (37.3)

BMI: Body Mass Index. SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value

[1] Within six months before date of first prescription

[2] Before Saxenda® first prescription date

[3] Dysglycaemia, hypertension, dyslipidaemia, obstructive sleep apnoea and/or other weight-related comorbidities

[4] Percentages based on the number of subjects with BMI ≥ 27 kg/m² and BMI < 30 kg/m²

[5] Subject [redacted] - [redacted] and Subject [redacted] - Gastro-oesophageal reflux disease (GORD)
[6] In patients with available BMI at treatment initiation
[7] Measured 16-24 weeks after first prescription date
[8] Based on last weight measurement observed within the index period
[9] Considering only patients that completed at least 12 weeks of treatment.
[10] Considering only patients that completed at least 12 weeks of treatment. Based on last weight measurement during the period of 4-12 weeks after prescription date.
Reference EOT: Table 14-10

Seventy patients (93.3%) treated by Saxenda® had a BMI > 30 kg/m^2, and 3 patients (4.0%) had a BMI comprised between 27 and 30 kg/m^2. Among these 3 patients, 1 had a [redacted], 1 had a GORD and 1 patient had no reported "weight-related comorbidity". The BMI could not be calculated as anthropometrics were not measured in 2 patients.

As presented in Table 10-15, among the 40 patients (53.3%) who completed at least 16 weeks of treatment, 11 (27.5%) patients were adherent to the stopping rule, 4 (10%) stopped treatment, and 2 patients (5%) were not adherent to the stopping rule. Non-adherence to the stopping rule was defined as continuing Saxenda® at 16 weeks of treatment when weight loss (measured between 16 and 24 weeks after first prescription) was less than 5%. For these 2 patients not treated according to the stopping rule, one patient lost [redacted] kg (2.6%) and the other one lost [redacted] kg (4.6%) from initial body weight. By the last weight measurement available, the former patient further lost [redacted] kg and the latter one regained [redacted] kg. Their respective weight loss from initial body weight were therefore [redacted] kg (11.9%) and [redacted] kg (2.7%).

For 23 patients (57.5%), adherence to the stopping rule was not evaluable as their body weight was not reported between 16 and 24 weeks after the first prescription.

As shown in Table 10-16, out of these 23 patients, 11 (47.8%) had lost ≥ 5% weight before 16 weeks of treatment and 4 patients (17.4%) who lost < 5% weight before 16 weeks either lost ≥ 5% weight after 24 weeks of treatment or stopped Saxenda®. Eight patients (34.8%) had their body weight not reported before 16 weeks of treatment. These 8 patients either lost ≥ 5% weight after 24 weeks of treatment (n=4) or stopped treatment after week 24 (n=2) or continued Saxenda® without body weight being measured after 24 weeks of treatment (n=2).

Table 10-16 Description of Saxenda® patients having more than 16 weeks of treatment and body weight measurement not taken between week 16 and 24

	Saxenda® Analysis Set (Italy)
Patients with over 16 weeks of treatment and bodyweight measurement not taken between week 16 to 24	23
Number of patients with more than 5% weight loss before 16 weeks of treatment, n (%)	11 (47.8)
Number of patients with less than 5% weight loss before 16 weeks of treatment, n (%)	4 (17.4)

	Saxenda® Analysis Set (Italy)
Body measurements not taken between first prescription to 16 weeks of treatment, n (%)	8 (34.8)
Patients with less than 5% weight loss before 16 weeks of treatment	
N	4
Number of patients with more than 24 weeks of treatment and more than 5% weight loss after 24 weeks of treatment, n (%)	2 (50.0)
Number of patients discontinuing treatment at 24 weeks of treatment	2 (50.0)
Patients with body measurements not taken between first prescription to 16 weeks of treatment, n (%)	
N	8
Number of patients with more than 24 weeks of treatment and with more than 5% weight loss after 24 weeks of treatment, n (%)	4 (50.0)
Number of patients with more than 24 weeks of treatment and body measurements not taken after 24 weeks of treatment, n (%)	2 (25.0)
Number of patients discontinuing treatment at 24 weeks of treatment	2 (25.0)

Reference EOT: Table 14-10

Among the 51 patients (68.0%) with at least 12 weeks of treatment, as shown in Table 10-15, 17 (33.3%) patients lost more than 5% weight between 4 and 12 weeks of treatment, 32 (62.7%) patients were adherent and 19 (37.3%) patients were non-adherent in reaching 3.0 mg at 12 weeks after first prescription date. As shown in Table 10-17, in the non-adherent patients, the mean percentage (±SD) of weight loss was -5.1 (±2.6) % when measured between 16 and 24 weeks after first prescription and - 8.3 (±5.8) % when using the last weight measurement of the index period. In the adherent patients, the mean percentage (±SD) weight loss was -5.5 (±3.0) % when measured between 16 and 24 weeks after first prescription and -10.3 (±6.1) % when using the last weight measurement of the index period.

Table 10-17 Mean percentage weight loss of Saxenda® patients having more than 16 weeks of treatment and body measurements not taken between week 16 and 24

	Saxenda® Analysis Set (Italy)	
	Non-adherent patients in reaching dose of 3.0 mg at 12 weeks (N=19)	**Adherent patients in reaching dose of 3.0 mg at 12 weeks (N=32)**
Mean percentage weight loss at 12 weeks of treatment based on last weight measurement during the period of 4-12 weeks after prescription date [1]		
N	16	18
Mean (SD)	-5.06 (2.584)	-5.47 (2.974)
Median	-5.3	-5.2
Q1,Q3	-6.9, -2.7	-7.7, -3.8
Missing	3	14
Mean percentage weight loss at 12 weeks of treatment based on last weight measurement observed within the index period [1]		
N	18	27
Mean (SD)	-8.26 (5.779)	-10.26 (6.065)
Median	-8.5	-8.0
Q1,Q3	-12.6, -3.8	-16.0, -6.0
Missing	1	5

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile
[1] Considering only patients that completed at least 12 weeks of treatment.
Reference EOT: Table 14-10

10.3.1.2 Secondary variables

Results on the use of Victoza® for weight management are presented in Table 10-18.

Table 10-18 Use of Victoza® for weight management

	Victoza® Analysis Set		
	Italy (N=75)	Germany (N=75)	Overall (N=150)
Number of patients with Victoza® prescriptions fulfilling at least one of the following criteria	2 (2.7)	0 (0.0)	2 (1.3)
Dose information 3.0 mg per day	1 (1.3)	0 (0.0)	1 (0.7)
Indication of weight management without T2DM[1][2]	1 (1.3)	0 (0.0)	1 (0.7)
Missing dose information [1]	1 (1.3)	0 (0.0)	1 (0.7)
Missing indication [1]	0 (0.0)	0 (0.0)	0 (0.0)

[1] At treatment initiation
[2] This subject (Subject ID=[redacted]) switched from [redacted] mg Victoza® dose to a [redacted] mg Saxenda® dose.
Reference EOT: Table 14-15

In Italy, one patient was reported as receiving a [redacted] mg dose and another patient was indicated Victoza® for weight management. This patient switched from Victoza® to a [redacted] mg Saxenda® dose as shown in Table 10-18.

Results on use of Saxenda® according to approved posology are presented in Table 10-19.

Table 10-19 Use of Saxenda® according to approved posology

	Saxenda® Analysis Set Italy (N=75)
Concomitant medication containing any other GLP-1 receptor agonists	
Number of Saxenda® patients with other GLP-1 receptor agonist prescribed during continued treatment with Saxenda® [1]	0 (0.0)
Duration of treatment (months) with Saxenda® [1]	
N	70
Mean (SD)	5.48 (4.300)
Median	4.0
Q1,Q3	2.2, 8.2
Missing	5
Duration of treatment (months) with Saxenda® – patients finished treatment at or before the index date [1]	
N	39
Mean (SD)	4.60 (3.090)
Median	4.2
Q1,Q3	1.9, 6.5
Missing	4

	Saxenda® Analysis Set Italy (N=75)
Duration of treatment (months) with Saxenda® – patients with treatment ongoing at index date [1]	
N	31
Mean (SD)	6.60 (5.303)
Median	3.8
Q1,Q3	2.2, 9.6
Missing	0
Duration of treatment with Saxenda® - categorisation [1]	
0-6 months	44 (58.7)
7-12 months	20 (26.7)
13-18 months	4 (5.3)
19-24 months	2 (2.7)
Ongoing	31 (41.3)
Missing	5 (6.7)
Patients who completed at least 12 weeks of treatment or have reached 3.0 mg even though they have not completed 12 weeks of treatment	
N	62
Number of non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date) [2]	19 (30.6)

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value
[1] Treatment duration is defined as: (Index date – Treatment initiation date + 1)/30.44 for patients continuing the treatment at index date and (last dose of treatment date – Treatment initiation date)/30.44 for patients discontinuing treatment during study period. Index is defined as 24 months after launch of Saxenda® in the country.
[2] Total number of patients considered for the denominator (N=62) includes only patients which, at index date, have completed at least 12 weeks of treatment or have reached 3.0 mg even though they have not completed 12 weeks of treatment. Patients which at index date have not completed 12 weeks of treatment and have not reached 3.0 mg dose were excluded from this calculation.
Reference EOT: Table 14-18

No patient was prescribed any other GLP-1 receptor agonist during treatment with Saxenda®.
The mean (±SD) treatment duration with Saxenda® was 5.5 (±4.3) months. Patients who finished treatment at or before the index date had a mean (±SD) treatment duration of 4.6 (±3.1) months (n=39, duration missing for 4 patients), whereas patients with ongoing treatment at index date reported a mean (±SD) treatment duration of 6.6 (±5.3) months with Saxenda® (n=31).The majority of patients (n=44, 58.7 %) reported a treatment duration equal or inferior to 6 months. A total of 19 (37.3%) patients were non-adherent as they did not reach the dose of 3.0 mg by 12 weeks after the first prescription date. Among the 62 patients who completed at least 12 weeks of treatment or had reached 3.0 mg even though they had not completed 12 weeks of treatment, 19 patients (30.6%) reached the 3.0 mg dose as shown in Table 10-19.

Results on use of Saxenda® according to approved posology by BMI at treatment initiation is presented in Table 10-20.

Table 10-20 Use of Saxenda® according to approved posology by body mass index at treatment initiation

	Saxenda® Analysis Set with initial BMI available Italy(N=73)		
	Body Mass Index categories (kg/m2)		
	≥27-<30 (N=3)	≥30-<40 (N=40)	≥40 (N=30)
Concomitant medication with any other GLP-1 receptor agonists			
Number of Saxenda® patients with other GLP-1 receptor agonists prescribed during continued treatment with Saxenda® [1]	0 (0.0)	0 (0.0)	0 (0.0)
Duration of treatment with Saxenda® (months) [1]			
N	3	36	30
Mean (SD)	5.89 (3.373)	5.99 (4.290)	5.01 (4.421)
Median	5.2	4.5	3.6
Q1,Q3	2.9, 9.6	3.0, 8.6	1.7, 6.5
Missing	0	4	0
Duration of treatment with Saxenda® (months) – patients finished treatment at or before the index date [1]			
N	1	20	18
Mean (SD)	5.19(-)	4.81 (3.556)	4.33 (2.656)
Median	5.2	4.0	3.9
Q1,Q3	5.2, 5.2	2.3, 6.9	1.9, 6.4
Missing	0	4	0
Duration of treatment with Saxenda® (months) – patients with treatment ongoing at index date [1]			
N	2	16	12
Mean (SD)	6.24 (4.692)	7.46 (4.768)	6.02 (6.226)
Median	6.2	8.3	3.6
Q1,Q3	2.9, 9.6	3.2, 9.5	1.6, 10.8
Missing	0	0	0

	Saxenda® Analysis Set with initial BMI available Italy(N=73)		
Duration of treatment with Saxenda® - categorisation [1]			
N	3	40	30
0-6 months	2 (66.7)	20 (50.0)	21 (70.0)
7-12 months	1 (33.3)	13 (32.5)	6 (20.0)
13-18 months	0 (0.0)	2 (5.0)	2 (6.7)
19-24 months	0 (0.0)	1 (2.5)	1 (3.3)
Ongoing	2 (66.7)	16 (40.0)	12 (40.0)
Missing	0 (0.0)	4 (10.0)	0 (0.0)
Adherence in reaching 3.0 mg by 12 weeks after first prescription date among patients who at index date, have completed at least 12 weeks of treatment or have reached 3.0 mg even though they have not completed 12 weeks of treatment			
N	3	35	24
Number of non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date) [2]	0 (0.0)	11 (31.4)	8 (33.3)

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value
[1] Treatment duration is defined as: (Index date – Treatment initiation date + 1)/30.44 for patients continuing the treatment at index date and (last dose of treatment date – Treatment initiation date)/30.44 for patients discontinuing treatment during study period. Index is defined as 24 months after launch of Saxenda® in the country.
[2] Total number of patients considered for the denominator (N=62) includes only patients which, at index date, have completed at least 12 weeks of treatment or have reached 3.0 mg even though they have not completed 12 weeks of treatment. Patients which at index date have not completed 12 weeks of treatment and have not reached 3.0 mg dose were excluded from this calculation.
Reference EOT: Table 14-21

The mean (±SD) treatment duration with Saxenda® was similar among patients with BMI ≥27-<30 kg/m^2 [5.9 (±3.4) months], and those with BMI ≥30-<40 kg/m^2 [5.9 (±4.3) months]; it was 5.0 (±4.4) months for patients with BMI ≥40 kg/m^2.When restricting to patients with ongoing treatment at index date, the mean (±SD) treatment duration was 6.2 (±4.7) months among patients with BMI ≥27-<30 kg/m^2, 7.5 (±4.8) months for patients with BMI ≥30-<40 kg/m^2, and 6.0 (±6.2) months for patients with BMI ≥40 kg/m^2.

The majority of patients (2 patients with BMI ≥27-<30 kg/m^2, 20 patients with BMI ≥30-<40 kg/m^2 and 21 patients with BMI ≥40 kg/m^2) treated with Saxenda® reported a treatment duration of less than 6 months. A total of 19 patients, including 11 patients with BMI ≥30-<40 kg/m^2 and 8 patients with BMI ≥40 kg/m^2 failed to reach 3.0 mg by 12 weeks after the first prescription date as shown in Table 10-20.

10.3.2 Summary of main results

Saxenda® was mainly prescribed to patients having obesity (70 patients out of 75, 93.3%). Three patients (4.0%) had a BMI between 27 and 30 kg/m^2. Among these 3 patients, 1 patient had no reported "weight-related comorbidities" , 1 had a [redacted] and 1 had GORD as weight-related comorbidity. The anthropometrics were not measured before treatment in 2 patients (2.7%).

With regards to adherence to the stopping rule, among the 40 patients (53.3%) who completed at least 16 weeks of treatment, 11 patients (27.5%) were adherent to the stopping rule as they continued treatment with at least 5% weight loss and 2 patients (5%) were not adherent as they continued treatment with less than 5% weight loss based on weight measured between 16 and 24 weeks after first prescription. For these 2 patients not treated according to the stopping rule, one patient lost [redacted] kg (2.6%) and the other one lost [redacted] kg (4.6%) from initial body weight. By the last weight measurement available, the former patient further lost [redacted] kg and the latter one regained [redacted] kg. Their respective weight loss from initial body weight were therefore [redacted] kg (11.9%) and [redacted] kg (2.7%).

At initial prescription, 70 patients (93.3%) were prescribed a dose of 0.6 mg. Among the 51 patients (68.0%) with at least 12 weeks of treatment, 32 patients (62.7%) were adherent and 19 patients (37.3%) were non-adherent in reaching 3.0 mg dose at 12 weeks after first prescription date.

No patient was prescribed any other GLP-1 receptor agonist during treatment with Saxenda®. The majority of patients treated with Saxenda® (58.7%) reported a treatment duration of less than 6 months. The proportions of patients with treatment duration of less than 6 months were 66.7% (2 out of 3), 50% (20 out of 40) and 70% (21 out of 30), among patients with BMI ≥27-<30 kg/m^2, ≥30-<40 kg/m^2, and ≥40 kg/m^2, respectively.

Overall 99.3% patients were prescribed Victoza® for T2DM with 100.0% patients in Germany and 98.7% patients in Italy. In Italy, one patient was reported as receiving a [redacted] mg dose and another patient was indicated Victoza® for weight management. There were no patients meeting these conditions in Germany.

10.4 Other analyses

Not applicable

10.5 Adverse events/adverse reactions

Not applicable

11 Discussion

11.1 Key results

All results related to Saxenda® were generated from 75 patients prescribed Saxenda® in Italy. Saxenda® was prescribed to 70 patients who had obesity (93.3%) and 3 patients (4.0%) who had a BMI comprised between 27 and 30 kg/m^2. Among those 3 patients, 1 patient had no reported "weight-related comorbidity"; the other 2 patients presented with [redacted] and GORD as weight-related comorbidity. The anthropometrics were not recorded at the initial prescription in 2 (2.7%) patients, for which the BMI could not be computed.

Among the 40 patients (53.3%) who completed at least 16 weeks of treatment, 11 (27.5%) patients were adherent to the stopping rule as they continued treatment with at least 5% weight loss from their initial body weight, and 2 (5%) patients continued treatment with less than 5% weight loss. For these 2 patients not treated according to the stopping rule, one patient lost [redacted] kg (2.6%) and the other one lost [redacted] kg (4.6%) from initial weight and when using the last weight measurement available, their respective weight loss were [redacted] kg (11.9%) and [redacted] kg (2.7%) as the latter regained [redacted] kg.

Among the 51 patients (68.0%) with at least 12 weeks of treatment, 32 (62.7%) patients were adherent in reaching 3.0 mg dose at 12 weeks after first prescription date.

No patient was reported with any other GLP-1 receptor agonist prescription during treatment with Saxenda®. The majority of patients treated with Saxenda® (58.7%) reported a treatment duration of less than 6 months.

All results related to Victoza® were generated from 150 patients prescribed Victoza® in Italy (n=75) and in Germany (n=75). Overall 99.3% patients were prescribed Victoza® for T2DM. In Italy, one patient was reported as receiving a [redacted] mg dose and another patient was indicated Victoza® for weight management. There were no patients meeting these conditions in Germany.

11.2 Limitations

Some limitations with regards to data completeness should be considered in this study, mainly for information related to weight and dose at follow-up for Saxenda® patients. The proportion of missing data for Saxenda® dose and body weight measurements between week 4 to 12 among patients having at least 12 weeks of treatment, reached 38.7% and 37.3%, respectively. This has led to a decrease in precision and an underestimation of endpoints such as adherence to the stopping rule and 3.0 mg dose reached at 12 weeks after first prescription date. This is a limitation inherent to retrospective study design. Some patients may have been treated by several different specialist physicians and complete information over the 24 months of retrospective follow-up may not have been accessible to the site.

The sampling strategy of this study was to approach a diversity of treatment settings and to include/exclude sites according to characteristics recorded in real-world prescriptions intelligence databases. Patients were not necessarily enrolled into the study in a consecutive chronological order. Also, physician could opt out of this study and it may have led to a selection bias. Sites' representativeness has therefore been evaluated throughout the study and *a posteriori* by observing the geographic distribution of the participating sites. It was evaluated that they reflected the geographical distribution of the prescriptions. In both Italy and Germany, the geographical distributions of the participating sites tend to represent the distribution of the prescriptions across these corresponding countries. The distributions of other parameters of the participating sites e.g. physician's specialty, have also been described. It was not possible to put these results into perspective due to lack of data on these parameters in the prescriptions intelligence databases. However, the distributions of locations being urban or rural, practice types, practice size, physician's specialty, and patient volumes showed diversity between the participating sites.

In Germany, it was possible to evaluate the patients' representativeness. The distributions of age and gender among Victoza® patients reflected the prescriptions' distributions as observed in the [redacted] database. In Italy, patients' representativeness could not be evaluated since the available Italian intelligence database did not describe age neither gender of patients prescribed Victoza® or Saxenda®. In both countries, patients from age categories ranging from 22 to 88 years and of either gender were recruited.

The representativeness evaluation should, however, be interpreted with caution because clinical data vs data from intelligence databases are based on two different metrics. Clinical data of this study describes distributions of either physicians or patients, whereas intelligence databases describe distributions of prescriptions. Moreover, the coverage of the intelligence databases does not encompass a wide range of practice settings and the time-periods covered by the intelligence database do not perfectly match the study period.

Information bias has been mitigated by the retrospective design. This study involves no intervention; treatment of patients considered eligible has been completed prior to the country-specific index date, and data was abstracted from established medical records. Thus, the knowledge about this study (and its conduct) could not have impacted the standard medical care, including the treatment with Saxenda® or Victoza®. Data collected from medical records therefore probably reflects real-world medical practice.

11.3 Interpretation

This study suggests that Saxenda® is mainly used according to its approved indication as only one patient having a BMI comprised between 27 and 30 kg/m^2 had no "weight-related comorbidity" reported. Additionally, pre-prescription BMI could not be calculated in only 2 patients (2.7%).

None of the 75 patients prescribed Saxenda® for weight management were prescribed any other GLP-1 receptor agonist during treatment with Saxenda®.

Some results are however more difficult to interpret due to incompleteness of medical charts especially for the documentation of height and weight and Saxenda® dose after treatment initiation. As a consequence, the proportion of patients being adherent with 3.0 mg dose reached at 12 weeks after first prescription and the proportion of patients being adherent to the stopping rule at 16 weeks of treatment are both probably underestimated. Moreover, the adherence to the stopping rule is an approximation. It was not evaluated by assessing weight loss after 12 weeks under 3.0 mg of Saxenda® dose but by assessing weight loss at 16 weeks of treatment regardless of Saxenda® dose.

Adherence to the stopping rule was not evaluable for 23 patients, as they had no reporting of body weight between 16 and 24 weeks after the first prescription. However, most of these 23 patients either lost weight before or after this time period or discontinued Saxenda® thereafter. Moreover, it has been observed that the 19 patients non-adherent to the dose escalation rule lost on average (±SD) 7.5 (±5.9) kg (8.3 %) of their pre-treatment body weight) during the index period.

The results related to Victoza® use were derived from 150 patients from 2 countries. A clear pattern was observed in both countries as the majority of patients were prescribed Victoza® for T2DM and only 2 patients were prescribed 3.0 mg per day or were indicated for weight management.

11.4 Generalisability

The representativeness evaluation has demonstrated that this study covers regions that reflect the distribution of prescriptions in both Italy and Germany as indicated by intelligence databases. Accordingly, patients' age and gender reflect the characteristics of patients being prescribed Victoza® in Germany. In terms of physician specialty distribution, the representativeness of the study sample was not established, due to limitations of the available intelligence databases. General practitioners belonged to the largest physician specialty group to refuse study participation in Germany. This study is also characterized by the diversity of sites, which are of different sizes and located both in urban and in rural areas. Patients were also diverse as in both countries, patients from age categories ranging from 22 to 88 years and of either gender were recruited. This diversity allows generalizing the results of this study to both genders, all adult age groups and urban as well as rural Italian and German populations.

12 Other information

Performing a pilot study proved to be valuable for carrying out this DUS in Germany and Italy. The feasibility analysis performed through the pilot study enabled adjustments for the full study´s objectives and methodology, thus enhancing the capability of addressing the proposed objectives.

The pilot study results demonstrated that recruitment of Saxenda® prescribers would be feasible in Italy but would be challenging in Germany due to low market penetration. In line with the results from the pilot study, it was proven feasible to enrol the *a priori* planned number of Saxenda® sites and number of Saxenda® treated patients in Italy, and Victoza® prescribing site and patients in both Germany and Italy. Likewise, the full study also reflected the pilot study data, showing adequate data availability and data quality for: estimating BMI; comorbidity endpoints at Saxenda® initiation; endpoints on adherence to dose escalation; duration of Saxenda® treatment; concomitant medication with other GLP-1 receptor agonists. The limited amount of documentation in both Italian and German medical charts for the full study, regarding Saxenda® stopping rule endpoints (number of patients with at least/less than 5% weight loss and continuing treatment) was due to limited availability of body weight measurements at 16-24 weeks; this, too, had already been flagged by the pilot study.

13 Conclusion

This DUS describes the real-world usage of liraglutide based on data from 75 patients prescribed Saxenda® in Italy and 150 patients prescribed Victoza® in Italy and Germany (75 patients each). A pilot study was performed beforehand and proved to be valuable for carrying out this study, as it enabled adjustments which enhanced full study´s capability of addressing the proposed objectives.

This DUS suggests that Saxenda® is mainly used according to its approved indication and its approved posology (despite some missing data related to the latter). The results on adherence to the stopping rule and in reaching 3.0 mg dose at 12 weeks after the first prescription are however difficult to interpret due to relative incompleteness of recorded data.

The majority of patients are prescribed Victoza® for T2DM diabetes as only one was prescribed Victoza® with an indication of weight management.

Despite the extent of missing data encountered and a potential for patient selection bias, the captured real-world data from Italy and Germany supports the prescriber adherence to the approved indication and posology for Saxenda® and Victoza®. The real-world data presented in this study does not give rise to new safety concerns for liraglutide.

14 Tables, figures and listings

Table 14-1 Characteristics of participating sites

Parameter	Italy (N=25)	Germany (N=16)
Primary specialty of participating physician, n(%)		
General practitioner	0 (0.0)	0 (0.0)
Cardiologist	0 (0.0)	1 (6.3)
Endocrinologist	11 (44.0)	2 (12.5)
Diabetes specialist	10 (40.0)	13 (81.3)
Obesity specialist	2 (8.0)	0 (0.0)
Internal Medicine	0 (0.0)	0 (0.0)
Other: Human Nutrition	1 (4.0)	0 (0.0)
Other: Gastroenterologist	1 (4.0)	0 (0.0)
Missing	0 (0.0)	0 (0.0)
Secondary specialty of participating physician in Italy, n(%)		
Diabetes and metabolic diseases	1 (4.0)	
Diabetology	11 (44.0)	
Diabetology and metabolic diseases	1 (4.0)	
Endocrinological and metabolic sciences	1 (4.0)	

Parameter	Italy (N=25)	Germany (N=16)
Food science and clinical nutrition	1 (4.0)	
Gastroenterology and endoscopy	1 (4.0)	
General medicine	1 (4.0)	
Geriatrics	1 (4.0)	
Internal medicine	3 (12.0)	
Internal medicine, endocrinology, food science	1 (4.0)	
Missing	2 (8.0)	
Nephrology, internal medicine	1 (4.0)	
Secondary specialty of participating physician in Germany, n(%)		
Diabetologist nutritional medicine physical medicine		1 (6.3)
Diabetology		12 (75.0)
Diabetology, sport medicine, resuscitation medicine, nutrition medicine		1 (6.3)
Endocrinologist, diabetologist, nutrition medicine, andrology, infectology		1 (6.3)
Missing		1 (6.3)
Practice type, n(%)		
Public hospital	18 (72.0)	0 (0.0)

Parameter	Italy (N=25)	Germany (N=16)
Private hospital	2 (8.0)	0 (0.0)
Academic centre	4 (16.0)	0 (0.0)
Medical centre	1 (4.0)	12 (75.0)
Office-based	0 (0.0)	4 (25.0)
Other	0 (0.0)	0 (0.0)
Missing	0 (0.0)	0 (0.0)

Italy: Geographical location of physician site, n(%)

Abruzzo	0 (0.0)
Aosta Valley	0 (0.0)
Apulia	0 (0.0)
Basilicata	0 (0.0)
Calabria	0 (0.0)
Campagna	3 (12.0)
Emilia Romagna	1 (4.0)
Friuli- Venezia Giulia	0 (0.0)
Lazio	6 (24.0)
Liguria	2 (8.0)

Parameter	Italy (N=25)	Germany (N=16)
Lombardy	5 (20.0)	
Marche	0 (0.0)	
Molise	0 (0.0)	
Piedmont	2 (8.0)	
Sardinia	1 (4.0)	
Sicily	2 (8.0)	
Trentino- South Tirol	0 (0.0)	
Tuscany	2 (8.0)	
Umbria	0 (0.0)	
Veneto	1 (4.0)	
Germany: Geographical location of physician site, n(%)		
Baden-Württemberg		0 (0.0)
Bavaria		1 (6.3)
Berlin		1 (6.3)
Brandenburg		1 (6.3)
Bremen		0 (0.0)
Hamburg		0 (0.0)

Parameter	Italy (N=25)	Germany (N=16)
Hesse		1 (6.3)
Lower Saxony		1 (6.3)
Mecklenburg-Vorpommern		0 (0.0)
North Rhine- Westphalia		4 (25.0)
Rhineland-Palatinate		1 (6.3)
Saarland		0 (0.0)
Saxony		2 (12.5)
Saxony-Anhalt		1 (6.3)
Schleswig-Holstein		1 (6.3)
Thuringia		0 (0.0)
Ba		2 (12.5)
Rural/Urban classification [1]		
Rural	9 (36.0)	6 (37.5)
Urban	16 (64.0)	10 (62.5)
Practice size		
Number of physicians practicing at site	202	79

Parameter	Italy (N=25)	Germany (N=16)
Mean (SD)	8.1 (13.85)	4.9 (9.04)
Median	3	2
Min, Max	1, 50	1, 38
Q1, Q3	2, 5	1, 4
Missing	0	0
1	5 (20.0)	5 (31.3)
2-5	14 (56.0)	8 (50.0)
>=6	6 (24.0)	3 (18.8)
Patient volume		
Total number of patients	1734	1220
Mean (SD)	69.4 (87.25)	76.3 (63.37)
Median	35	53
Min, Max	4, 300	4, 200
Q1, Q3	10, 70	29, 115
Missing	0	0
1-10	7 (28.0)	2 (12.5)
11-25	3 (12.0)	2 (12.5)

Parameter	Italy (N=25)	Germany (N=16)
26-50	7 (28.0)	4 (25.0)
>=50	8 (32.0)	8 (50.0)
Number of patients prescribed Saxenda		
Total number of patients	268	0
Mean (SD)	10.7 (15.40)	-
Median	5	-
Min, Max	0, 60	-
Q1, Q3	0, 14	-
Missing	0	16
0	9 (36.0)	16 (100.0)
1-10	9 (36.0)	0
11-25	3 (12.0)	0
26-50	3 (12.0)	0
>=50	1 (4.0)	0
Number of patients prescribed Victoza		
Total number of patients	1466	1220

Parameter	Italy (N=25)	Germany (N=16)
Mean (SD)	58.6 (83.63)	76.3 (63.37)
Median	30	53
Min, Max	0, 280	4, 200
Q1, Q3	4, 50	29, 115
Missing	0	0
0	3 (12.0)	0
1-10	9 (36.0)	2 (12.5)
11-25	0	2 (12.5)
26-50	7 (28.0)	4 (25.0)
>=50	6 (24.0)	8 (50.0)

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value
[1] Rural/urban classification based on metropolitan area classification for Italy/Germany

Table 14-2 Characteristics of non-participating sites

Parameter	Italy	Germany	Total
Total number of sites approached, N	181 (100.0)	238 (100.0)	419 (100.0)
Total number of non-participating sites, n (%)	156 (86.2)	222 (93.3)	378 (90.2)
Primary specialty of non-participating physician, n(%)			
Cardiovascular Disease	10 (6.4)	0 (0.0)	10 (2.6)
Endocrinology	22 (14.1)	17 (7.7)	39 (10.3)
Endocrinology/Diabetes/Metab	102 (65.4)	68 (30.6)	170 (45.0)
General Practice/Medicine	3 (1.9)	96 (43.2)	99 (26.2)
Hepatology	1 (0.6)	1 (0.5)	2 (0.5)
Internal Medicine	13 (8.3)	38 (17.1)	51 (13.5)
Missing	0 (0.0)	1 (0.5)	1 (0.3)
Nephrology	2 (1.3)	0 (0.0)	2 (0.5)
Neurology	1 (0.6)	0 (0.0)	1 (0.3)
Ophthalmology	1 (0.6)	0 (0.0)	1 (0.3)
Other	1 (0.6)	0 (0.0)	1 (0.3)

Parameter	Italy	Germany	Total
Respiratory	0 (0.0)	1 (0.5)	1 (0.3)
Reasons for not participating, n (%)			
Competing Studies	1 (0.6)	1 (0.5)	2 (0.5)
Lack of Staff/Resources	5 (3.2)	11 (5.0)	16 (4.2)
Lack of Subject Population	8 (5.1)	14 (6.3)	22 (5.8)
Long Ethics/RA Timelines	0 (0.0)	1 (0.5)	1 (0.3)
No Conduct of this Study Type	3 (1.9)	6 (2.7)	9 (2.4)
No Longer Doing Research	1 (0.6)	6 (2.7)	7 (1.9)
No Time/Not Taking Studies	10 (6.4)	17 (7.7)	27 (7.1)
No reason provided	106 (67.9)	97 (43.7)	203 (53.7)
Not Interested	19 (12.2)	61 (27.5)	80 (21.2)
PI No Longer At Site	1 (0.6)	1 (0.5)	2 (0.5)
PI Retired	1 (0.6)	6 (2.7)	7 (1.9)
Replacement PI	1 (0.6)	0 (0.0)	1 (0.3)
Study Design	0 (0.0)	1 (0.5)	1 (0.3)

Italy: Geographical location of physician site, n(%)

Parameter	Italy	Germany	Total
Abruzzo	5 (3.2)		
Basilicata	3 (1.9)		
Calabria	6 (3.8)		
Campania	15 (9.6)		
Emilia Romagna	7 (4.5)		
Friuli-Venezia Giulia	1 (0.6)		
Lazio	8 (5.1)		
Liguria	6 (3.8)		
Lombardia	30 (19.2)		
Marche	1 (0.6)		
Molise	2 (1.3)		
Piemonte	11 (7.1)		
Puglia	12 (7.7)		
Sardegna	7 (4.5)		
Sicilia	19 (12.2)		
Toscana	9 (5.8)		
Trentino-Alto Adige	2 (1.3)		
Umbria	1 (0.6)		

Parameter	Italy	Germany	Total
Veneto	11 (7.1)		

Germany: Geographical location of physician site, n(%)

Missing		2	
Baden Wuerttemberg		17 (7.7)	
Bayern		32 (14.5)	
Berlin		9 (4.1)	
Brandenburg		4 (1.8)	
Hessen		3 (1.4)	
Mecklenburg Vorpommern		20 (9.1)	
Niedersachsen		13 (5.9)	
Nordrhein Westfalen		29 (13.2)	
Rheinland Pfalz		30 (13.6)	
Saarland		3 (1.4)	
Sachsen		14 (6.4)	
Sachsen Anhalt		9 (4.1)	
Schleswig Holstein		3 (1.4)	
Thueringen		34 (15.5)	

Table 14-3 Availability of parameters in Saxenda® patients

Parameter	Italy (n=75)
Number of Saxenda® patients with available parameter	
Age	75 (100.0)
Gender	75 (100.0)
Comorbidities	75 (100.0)
Adult height [1]	74 (98.7)
Body weight at first Saxenda® prescription [2]	73 (97.3)
Body weight at 16-24 weeks of treatment	17 (22.7)
Indication prescribed	75 (100.0)
Current dose at 4-12 weeks [3]	29 (38.7)
Start date	29 (38.7)
Current dose at 16-24 weeks [4]	13 (17.3)
Start date	13 (17.3)
Concomitant medication with GLP-1 receptor agonists (Brand name and start date)	75 (100.0)
All of the above	3 (4.0)

[1] At Week 0
[2] Latest recording within six months before date of first prescription of Saxenda®
[3] Assessed 4-12 weeks after first prescription date. A total of N=51 patients had at least 12 weeks of treatment.
[4] Assessed 16-24 weeks after first prescription date. A total of N=40 patients had at least 16 weeks of treatment.

Table 14-4 Availability of parameters in Victoza patients

Parameter	Italy (N=75)	Germany (N=75)	Total (N=150)
Number of Victoza patients with available parameter n(%)			
Age	75 (100.0)	75 (100.0)	150 (100.0)
Gender	75 (100.0)	75 (100.0)	150 (100.0)
Initial dose prescribed	74 (98.7)	75 (100.0)	149 (99.3)
Indication prescribed	75 (100.0)	75 (100.0)	150 (100.0)
Dose escalation of Victoza	75 (100.0)	75 (100.0)	150 (100.0)
All of the above	74 (98.7)	75 (100.0)	149 (99.3)

Table 14-5 Patient Disposition

	Italy	Germany	Overall
Total number of patients prescreened, n	261	179	440
Number of patients prescreened and not enrolled, n (%) [1]	111 (42.5)	104 (58.1)	215 (48.9)
Reason for non-enrolment			
Patient Refusal	11 (9.9)	15 (14.4)	26 (12.1)
Patient did not meet inclusion criteria			
Initiation of Saxenda or Victoza during Index period, n (%) [2]	9 (8.1)	18 (17.3)	27 (12.6)
Informed consent obtained, n (%) [2]	4 (3.6)	5 (4.8)	9 (4.2)
Patient met exclusion criterion			
Patients or physicians who previously participated in interventional programs for Saxenda or Victoza, n (%) [2]	0 (0.0)	0 (0.0)	0 (0.0)
Patient participated in pilot study, n (%) [2]	0 (0.0)	0 (0.0)	0 (0.0)
Not included because site reached recruitment target, n (%)	88 (79.3)	67 (64.4)	155 (72.1)
Missing data	0 (0.0)	2 (1.9)	2 (0.9)
Patient not successfully contacted	3 (2.7)	2 (1.9)	5 (2.3)
Number of patients enrolled in Full analysis set, n (%) [1]	150 (57.5)	75 (41.9)	225 (51.1)
Study duration for patients in Full analysis set (months)			
N	149	75	224
Mean (SD)	11.03 (6.422)	12.90 (7.365)	11.66 (6.793)
Median	10.4	13	10.65
Q1, Q3	6.7, 16	7.3, 20.2	6.75, 17.55
Min, Max	0.4, 23.2	0.2, 23.5	0.2, 23.5

	Italy	Germany	Overall
Missing	1	0	1
Number of patients enrolled in Saxenda analysis set, n (%) [3]	75 (50.0)		75 (33.3)
Study duration for patients in Saxenda analysis set (months) [4]			
N	75		75
Mean (SD)	10.38 (6.434)		10.38 (6.434)
Median	9.1		9.1
Q1, Q3	4.8, 15.8		4.8, 15.8
Min, Max	0.4, 23.2		0.4, 23.2
Missing	0		0
Number of patients enrolled in Victoza analysis set, n (%) [3]	75 (50.0)	75 (100.0)	150 (66.7)
Study duration for patients in Victoza analysis set (months) [4]			
N	74	75	149
Mean (SD)	11.70 (6.385)	12.90 (7.365)	12.30 (6.899)
Median	10.9	13	11.2
Q1, Q3	7, 17.7	7.3, 20.2	7.3, 18.7
Min, Max	0.7, 22.8	0.2, 23.5	0.2, 23.5
Missing	1	0	1
Number of patients that withdrew during study period in Full analysis set, n (%) [3]	0 (0.0)	0 (0.0)	0 (0.0)
Reason for study discontinuation			
Withdraw of consent n (%)	0 (0.0)	0 (0.0)	0 (0.0)

	Italy	Germany	Overall
Investigator decision n (%)	0 (0.0)	0 (0.0)	0 (0.0)
Other n (%)	0 (0.0)	0 (0.0)	0 (0.0)
Number of patients who discontinued Saxenda, n (%) [5]	43 (57.3)		43 (57.3)
Duration of Saxenda treatment (months) during the index period [6]			
N	39		39
Mean (SD)	4.59 (3.095)		4.59 (3.095)
Median	4.2		4.2
Q1, Q3	1.9, 6.5		1.9, 6.5
Min, Max	0.6, 16.3		0.6, 16.3
Missing	4		4
Number of patients who discontinued Victoza, n (%) [7]	5 (6.7)	5 (6.7)	10 (6.7)
Duration of Victoza treatment (months) during the index period [6]			
N	5	5	10
Mean (SD)	8.00 (6.092)	5.62 (3.114)	6.81 (4.731)
Median	7	5.3	6.15
Q1, Q3	4.7, 7.8	2.7, 7.9	2.7, 7.9
Min, Max	2.3, 18.2	2.6, 9.6	2.3, 18.2
Missing	0	0	0

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value
Index is defined as 24 months after launch of Saxenda in the country
[1] Percentage based on total number of patients approached.
[2] Percentage based on number of patients approached and not enrolled
[3] Percentage based on number of patients enrolled in Full analysis set

[4] Study follow-up duration is defined as: (Index date – Treatment initiation date + 1)/30.44
[5] Percentage based on number of patients enrolled in Saxenda analysis set
[6] Treatment duration is defined as: (Index date – Treatment initiation date + 1)/30.44 for patients continuing the treatment at index date and (last dose of treatment date – Treatment initiation date)/30.44 for patients discontinuing treatment during study period
[7] Percentage based on number of patients enrolled in Victoza analysis set

Table 14-6 Patient Demographics of enrolled vs non-enrolled patients

	Enrolled patients			Non-enrolled patients			Total (N=440)
	Italy (N=150)	Germany (N=75	Overall (N=225)	Italy (N=111)	Germany (N=104)	Overall (N=215)	
Age (years)[1]							
n	150	75	225	111	104	215	440
Mean (SD)	59.3 (12.56)	58.6 (11.42)	59.1 (12.17)	58.7 (11.03)	58.0 (10.87)	58.4 (10.93)	58.7 (11.57)
Median	59	61	60	59	59	59	59
Min, Max	20, 83	34, 88	20, 88	19, 82	23, 82	19, 82	19, 88
Q1, Q3	51, 70	52, 66	52, 68	51, 68	51, 65	51, 66	52, 67
Missing	0	0	0	0	0	0	0
Age categories, n (%)							
<18	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
18-29	2 (1.3)	0 (0.0)	2 (0.9)	2 (1.8)	1 (1.0)	3 (1.4)	5 (1.1)
30-39	8 (5.3)	5 (6.7)	13 (5.8)	3 (2.7)	5 (4.8)	8 (3.7)	21 (4.8)
40-49	21 (14.0)	10 (13.3)	31 (13.8)	17 (15.3)	16 (15.4)	33 (15.3)	64 (14.5)
50-59	46 (30.7)	20 (26.7)	66 (29.3)	36 (32.4)	31 (29.8)	67 (31.2)	133 (30.2)
60-64	14 (9.3)	17 (22.7)	31 (13.8)	14 (12.6)	24 (23.1)	38 (17.7)	69 (15.7)
65-69	20 (13.3)	11 (14.7)	31 (13.8)	21 (18.9)	12 (11.5)	33 (15.3)	64 (14.5)
70-74	21 (14.0)	8 (10.7)	29 (12.9)	15 (13.5)	9 (8.7)	24 (11.2)	53 (12.0)
>=75	18 (12.0)	4 (5.3)	22 (9.8)	3 (2.7)	6 (5.8)	9 (4.2)	31 (7.0)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

	Enrolled patients			Non-enrolled patients			Total
Gender							
Female	86 (57.3)	35 (46.7)	121 (53.8)	56 (50.5)	50 (48.1)	106 (49.3)	227 (51.6)
Male	64 (42.7)	40 (53.3)	104 (46.2)	55 (49.5)	54 (51.9)	109 (50.7)	213 (48.4)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value
[1] Age is calculated as year of treatment initiation minus year of birth as reported in the CRF

Table 14-7 Patient Demographics by Country

	Full Analysis Set			Victoza Analysis Set			Saxenda® Analysis Set
	Italy (N=150)	Germany (N=75)	Overall (N=225)	Italy (N=75)	Germany (N=75)	Overall (N=150)	Italy (N=75)
Age (years)[1]							
N	150	75	225	75	75	150	75
Mean (SD)	59.3 (12.56)	58.6 (11.42)	59.1 (12.17)	63.1 (11.98)	58.6 (11.42)	60.9 (11.88)	55.5 (12.02)
Median	59	61	60	66	61	62	56
Min, Max	20, 83	34, 88	20, 88	20, 83	34, 88	20, 88	22, 78
Q1, Q3	51, 70	52, 66	52, 68	56, 72	52, 66	54, 70	48, 65
Missing	0	0	0	0	0	0	0
Age categories, n (%)							
<18	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
18-29	2 (1.3)	0 (0.0)	2 (0.9)	1 (1.3)	0 (0.0)	1 (0.7)	1 (1.3)
30-39	8 (5.3)	5 (6.7)	13 (5.8)	1 (1.3)	5 (6.7)	6 (4.0)	7 (9.3)
40-49	21 (14.0)	10 (13.3)	31 (13.8)	7 (9.3)	10 (13.3)	17 (11.3)	14 (18.7)
50-59	46 (30.7)	20 (26.7)	66 (29.3)	19 (25.3)	20 (26.7)	39 (26.0)	27 (36.0)
60-64	14 (9.3)	17 (22.7)	31 (13.8)	7 (9.3)	17 (22.7)	24 (16.0)	7 (9.3)
65-69	20 (13.3)	11 (14.7)	31 (13.8)	12 (16.0)	11 (14.7)	23 (15.3)	8 (10.7)
70-74	21 (14.0)	8 (10.7)	29 (12.9)	15 (20.0)	8 (10.7)	23 (15.3)	6 (8.0)
>=75	18 (12.0)	4 (5.3)	22 (9.8)	13 (17.3)	4 (5.3)	17 (11.3)	5 (6.7)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

	Full Analysis Set			Victoza Analysis Set			Saxenda® Analysis Set
Gender							
Female	86 (57.3)	35 (46.7)	121 (53.8)	38 (50.7)	35 (46.7)	73 (48.7)	48 (64.0)
Male	64 (42.7)	40 (53.3)	104 (46.2)	37 (49.3)	40 (53.3)	77 (51.3)	27 (36.0)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value.
[1] Age is calculated as year of treatment initiation minus year of birth as reported in the CRF

Table 14-8 Saxenda® Anthropometric Patient Characteristics at Treatment Initiation

	Saxenda® Analysis Set
	Italy (N=75)
Height (cm) [1]	
N	74
Mean (SD)	166.63 (9.785)
Median	165.0
Min, Max	144.5, 187.0
Q1, Q3	159.0, 175.0
Missing	1
Weight (kg) [2]	
N	73
Mean (SD)	106.32 (22.445)
Median	105.0
Min, Max	68.0, 186.0
Q1, Q3	88.0, 119.0
Missing	2
Body mass index (kg/m2)	
N	73
Mean (SD)	38.17 (6.909)
Median	36.9
Min, Max	28.4, 68.3

	Saxenda® Analysis Set
Q1, Q3	32.6, 42.6
Missing	2
Body mass index categories (kg/m2)	
<18.5	0 (0.0%)
≥18.5-<25	0 (0.0%)
≥25-<27	0 (0.0%)
≥27-<30	3 (4.0%)
≥30-<40	40 (53.3%)
≥40	30 (40.0%)
Missing	2 (2.7%)

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value.
[1] At Week 0
[2] Latest recording within six months before date of first prescription of Saxenda®

Table 14-9 Saxenda® Patient Comorbidities Ongoing at Treatment Initiation

	Saxenda® Analysis Set
	Italy (N=75)
Total number of weight related comorbidities ongoing at treatment initiation, n (%)	
0	20 (26.7)
1	21 (28.0)
2	17 (22.7)
3	12 (16.0)
4	4 (5.3)
>4	1 (1.3)
Dysglycaemia, n (%) [1]	18 (24.0)
Hypertension, n (%)	31 (41.3)
Dyslipidaemia, n (%)	29 (38.7)

	Saxenda® Analysis Set
	Italy (N=75)
Obstructive sleep apnoea, n (%)	12 (16.0)
Other weight-related comorbidities, n (%)	19 (25.3)
Coronary Artery Disease (Cad)	1 (1.3)
Gallbladder Disease	2 (2.7)
Gastro-Oesophageal Reflux Disease (Gerd)	4 (5.3)
Osteoarthritis/Osteoarthrosis	4 (5.3)
[redacted]	2 (2.7)
	1 (1.3)
	1 (1.3)
Hypothyroidism	1 (1.3)
Vertebral column disorders	3 (4.0)
Non-alcoholic fatty liver disease	6 (8.0)
Vitamin D Deficiency	1 (1.3)

[1] Dysglycaemia refers to type 2 diabetes or prediabetes

Table 14-10 Use of Saxenda® According to Approved Indication

	Saxenda® Analysis Set
	Italy (N=75)
BMI and comorbidities	
BMI ≥ 30 kg/m² [1]	70 (93.3)
BMI ≥ 27 kg/m² and BMI < 30 kg/m² [1]	3 (4.0)
≥ 1 relevant comorbidity [2,3,4]	2 (66.7)
Dysglycaemia [4]	0 (0.0)
Hypertension [4]	0 (0.0)
Dyslipidaemia [4]	0 (0.0)
Obstructive sleep apnoea [4]	0 (0.0)
Other weight-related comorbidities [4]	2 (66.7)
No relevant comorbidity [2,3]	1 (33.3)
BMI < 27 kg/m² [1]	0 (0.0)
BMI not measured [1]	2 (2.7)
Stopping rule [5]	

	Saxenda® Analysis Set
	Italy (N=75)
Completed at least 16 weeks of treatment before index date	40 (53.3)
At least 5% weight loss and continuing treatment [6]	11 (27.5)
Less than 5% weight loss and continuing treatment [6]	2 (5.0)
Body measurements not taken between week 16 to 24	23 (57.5)
Mean weight loss (%) [7] in patients not treated according to stopping rule	
N	2
Mean (SD)	-5.65 (4.738)
Median	-5.6
Min,Max	-9.0, -2.3
Q1,Q3	-9.0, -2.3
Missing	0
Number of patients that had at least 12 weeks of treatment	51 (68.0)
Number of non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date) [8]	19 (37.3)

	Saxenda® Analysis Set
	Italy (N=75)
Number of adherent patients (3.0 mg reached by 12 weeks after first prescription date) [8]	32 (62.7)
Number of patients with more than 5% weight loss at 4-12 weeks of treatment, n (%) [9]	17 (33.3)
Body measurements not taken between week 4 to 12 [8]	19 (25.3)
Mean weight loss at 12 weeks of treatment in patients that have not reached 3.0 mg Saxenda® dose at 12 weeks [9]	
N	16
Mean (SD)	-5.08 (2.783)
Median	-5.0
Min,Max	-11.0, -1.2
Q1,Q3	-6.9, -2.9
Missing	3
Mean percentage weight loss at 12 weeks of treatment in patients that have not reached 3.0 mg Saxenda dose at 12 weeks [9]	

	Saxenda® Analysis Set
	Italy (N=75)
N	16
Mean (SD)	-5.06 (2.584)
Median	-5.3
Min,Max	-9.2, -1.2
Q1,Q3	-6.9, -2.7
Missing	3
Mean weight loss at 12 weeks of treatment in patients that have reached 3.0 mg Saxenda® dose at 12 weeks [9]	
N	18
Mean (SD)	-5.27 (2.647)
Median	-4.9
Min,Max	-11.0, -1.0
Q1,Q3	-7.0, -3.5
Missing	14

	Saxenda® Analysis Set
	Italy (N=75)
Mean percentage weight loss at 12 weeks of treatment in patients that have reached 3.0 mg Saxenda dose at 12 weeks [9]	
N	18
Mean (SD)	-5.47 (2.974)
Median	-5.2
Min,Max	-12.2, -0.7
Q1,Q3	-7.7, -3.8
Missing	14
Mean weight loss in patients that have not reached 3.0 mg Saxenda® dose at 12 weeks [7]	
N	18
Mean (SD)	-7.47 (5.960)
Median	-8.0
Min,Max	-17.5, 4.0
Q1,Q3	-13.0, -2.3
Missing	1

	Saxenda® Analysis Set
	Italy (N=75)
Mean percentage weight loss in patients that have not reached 3.0 mg Saxenda® dose at 12 weeks [7]	
N	18
Mean (SD)	-8.26 (5.779)
Median	-8.5
Min,Max	-16.9, 3.9
Q1,Q3	-12.6, -3.8
Missing	1
Mean weight loss in patients that have reached 3.0 mg Saxenda® dose at 12 weeks [7]	
N	27
Mean (SD)	-9.71 (7.207)
Median	-8.0
Min,Max	-33.0, -1.0
Q1,Q3	-13.5, -5.0
Missing	5

	Saxenda® Analysis Set
	Italy (N=75)
Mean percentage weight loss in patients that have reached 3.0 mg Saxenda dose at 12 weeks [7]	
N	27
Mean (SD)	-10.26 (6.065)
Median	-8.0
Min,Max	-26.4, -1.7
Q1,Q3	-16.0, -6.0
Missing	5
Mean weight loss in all patients [7]	
N	60
Mean (SD)	-7.73 (6.846)
Median	-5.5
Min,Max	-33.0, 4.0
Q1,Q3	-11.0, -3.2
Missing	15

	Saxenda® Analysis Set
	Italy (N=75)
Mean percentage weight loss in all patients [7]	
N	60
Mean (SD)	-8.33 (5.950)
Median	-6.7
Min,Max	-26.4, 3.9
Q1,Q3	-11.8, -4.5
Missing	15
Number of patients that completed at least 16 weeks of treatment, n (%)	40 (53.3)
Number of patients with more than 5% weight loss before 16 weeks of treatment, n (%) [10]	23 (57.5)
Body measurements not taken between first prescription to 16 weeks of treatment, n (%) [10]	10 (25.0)
Number of patients that had more than 24 weeks of treatment, n (%)	29 (38.7)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%) [11]	17 (58.6)
Body measurements not taken after 24 weeks of treatment, n (%) [11]	7 (24.1)

	Saxenda® Analysis Set
	Italy (N=75)
Number of patients that had more than 16 weeks of treatment and body measurements were not taken between week 16 to 24, n (%)	23 (30.7)
Number of patients with more than 5% weight loss before 16 weeks of treatment, n (%)	11 (47.8)
Number of patients with less than 5% weight loss before 16 weeks of treatment, n (%)	4 (17.4)
Number of patients that had more than 24 weeks of treatment, n (%)	2 (50.0)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%)	2 (100.0)
Body measurements not taken after 24 weeks of treatment, n (%)	0 (0.0)
Body measurements not taken between first prescription to 16 weeks of treatment, n (%)	8 (34.8)
Number of patients that had more than 24 weeks of treatment, n (%)	6 (300.0)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%)	4 (66.7)
Body measurements not taken after 24 weeks of treatment, n (%)	2 (33.3)
Number of patients that had more than 24 weeks of treatment and body measurements were not taken between week 16 to 24, n (%)	16 (21.3)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%) [12]	9 (56.3)
Body measurements not taken after 24 weeks of treatment, n (%) [12]	3 (18.8)

BMI: Body Mass Index. SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value.
[1] Within six months before date of first prescription.
[2] Before Saxenda first prescription date.
[3] Dysglycaemia, hypertension, dyslipidaemia, obstructive sleep apnoea and/or other weight-related comorbidities.
[4] Percentages based on the number of subjects with BMI ≥ 27 kg/m² and BMI < 30 kg/m².
[5] In patients with available BMI at treatment initiation.
[6] Measured 16-24 weeks after first prescription date.
[7] Based on last weight measurement observed within the index period.
[8] Considering only patients that completed at least 12 weeks of treatment.
[9] Considering only patients that completed at least 12 weeks of treatment. Based on last weight measurement during the period of 4-12 weeks after prescription date.
[10] Percentages based on number of subjects that completed at least 16 weeks of treatment. Based on last weight measurement before 16 weeks of treatment.
[11] Percentages based on number of subjects that completed more than 24 weeks of treatment. Based on last weight measurement after 24 weeks of treatment.

Table 14-11 Use of Saxenda® According to Approved Indication by Patient Sex

	Saxenda® Analysis Set	
	Italy (N=75)	
	Patient Gender	
	Male (N=27)	Female (N=48)
BMI and comorbidities		
BMI ≥ 30 kg/m² [1]	26 (96.3)	44 (91.7)
BMI ≥ 27 kg/m² and BMI < 30 kg/m² [1]	0 (0.0)	3 (6.3)
≥ 1 relevant comorbidity [2,3,4]	0	2 (66.7)
Dysglycaemia [4]	0	0 (0.0)
Hypertension [4]	0	0 (0.0)
Dyslipidaemia [4]	0	0 (0.0)
Obstructive sleep apnoea [4]	0	0 (0.0)
Other weight-related comorbidities [4]	0	2 (66.7)
No relevant comorbidity [2,3]	0	1 (33.3)
BMI < 27 kg/m² [1]	0 (0.0)	0 (0.0)
BMI not measured [1]	1 (3.7)	1 (2.1)
Stopping rule [5]		
Completed at least 16 weeks of treatment before index date	11 (40.7)	29 (60.4)
At least 5% weight loss and continuing treatment [6]	2 (18.2)	9 (31.0)

	Saxenda® Analysis Set
Less than 5% weight loss and continuing treatment [6]	0 (0.0)	2 (6.9)
Body measurements not taken between week 16 to 24	6 (54.5)	17 (58.6)
Mean weight loss (%) [7] in patients not treated according to stopping rule		
N	0	2
Mean (SD)	-	-5.65 (4.738)
Median	-	-5.6
Min,Max	-	-9.0, -2.3
Q1,Q3	-	-9.0, -2.3
Missing	0	0
Number of patients that had at least 12 weeks of treatment	16 (59.3)	35 (72.9)
Number of non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date) [8]	3 (18.8)	16 (45.7)
Number of adherent patients (3.0 mg reached by 12 weeks after first prescription date) [8]	13 (81.3)	19 (54.3)
Number of patients with more than 5% weight loss at 4-12 weeks of treatment, n (%) [9]	1 (6.3)	16 (45.7)

	Saxenda® Analysis Set	
Body measurements not taken between week 4 to 12 [8]	10 (37.0)	9 (18.8)
Mean weight loss at 12 weeks of treatment in patients that have not reached 3.0 mg Saxenda® dose at 12 weeks [9]		
N	3	13
Mean (SD)	-4.33 (2.603)	-5.25 (2.894)
Median	-4.2	-5.0
Min,Max	-7.0, -1.8	-11.0, -1.2
Q1,Q3	-7.0, -1.8	-6.7, -4.0
Missing	0	3
Mean weight loss at 12 weeks of treatment in patients that have reached 3.0 mg Saxenda® dose at 12 weeks [9]		
N	4	14
Mean (SD)	-2.63 (1.797)	-6.03 (2.376)
Median	-2.3	-5.2
Min,Max	-5.0, -1.0	-11.0, -3.5
Q1,Q3	-4.0, -1.3	-8.0, -4.3
Missing	9	5
Mean weight loss in patients that have not reached 3.0 mg Saxenda® dose at 12 weeks [7]		

	Saxenda® Analysis Set	
N	3	15
Mean (SD)	-5.10 (4.557)	-7.95 (6.223)
Median	-3.2	-9.0
Min,Max	-10.3, -1.8	-17.5, 4.0
Q1,Q3	-10.3, -1.8	-14.0, -2.3
Missing	0	1
Mean weight loss in patients that have reached 3.0 mg Saxenda® dose at 12 weeks [7]		
N	11	16
Mean (SD)	-9.32 (8.730)	-9.98 (6.248)
Median	-8.0	-8.8
Min,Max	-33.0, -1.0	-28.0, -3.0
Q1,Q3	-11.0, -5.0	-13.6, -5.0
Missing	2	3
Mean weight loss in all patients [7]		
N	22	38
Mean (SD)	-7.23 (8.140)	-8.01 (6.075)
Median	-5.0	-7.0
Min,Max	-33.0, 2.0	-28.0, 4.0
Q1,Q3	-8.0, -3.0	-13.0, -4.4
Missing	5	10

	Saxenda® Analysis Set	
Number of patients that completed at least 16 weeks of treatment, n (%)	11 (40.7)	29 (60.4)
Number of patients with more than 5% weight loss before 16 weeks of treatment, n (%) [10]	2 (18.2)	21 (72.4)
Body measurements not taken between first prescription to 16 weeks of treatment, n (%) [10]	6 (54.5)	4 (13.8)
Number of patients that had more than 24 weeks of treatment, n (%)	7 (25.9)	22 (45.8)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%) [11]	5 (71.4)	12 (54.5)
Body measurements not taken after 24 weeks of treatment, n (%) [11]	1 (14.3)	6 (27.3)
Number of patients that had more than 16 weeks of treatment and body measurements were not taken between week 16 to 24, n (%)	6 (22.2)	17 (35.4)
Number of patients with more than 5% weight loss before 16 weeks of treatment, n (%)	1 (16.7)	10 (58.8)
Number of patients with less than 5% weight loss before 16 weeks of treatment, n (%)	1 (16.7)	3 (17.6)
Number of patients that had more than 24 weeks of treatment, n (%)	1 (100.0)	1 (33.3)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%)	1 (100.0)	1 (100.0)
Body measurements not taken after 24 weeks of treatment, n (%)	0 (0.0)	0 (0.0)

	Saxenda® Analysis Set	
Body measurements not taken between first prescription to 16 weeks of treatment, n (%)	4 (66.7)	4 (23.5)
Number of patients that had more than 24 weeks of treatment, n (%)	3 (75.0)	3 (75.0)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%)	3 (100.0)	1 (33.3)
Body measurements not taken after 24 weeks of treatment, n (%)	0 (0.0)	2 (66.7)
Number of patients that had more than 24 weeks of treatment and body measurements were not taken between week 16 to 24, n (%)	5 (18.5)	11 (22.9)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%)	4 (80.0)	5 (45.5)
Body measurements not taken after 24 weeks of treatment, n (%)	0 (0.0)	3 (27.3)

BMI: Body Mass Index. SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value.
[1] Within six months before date of first prescription.
[2] Before Saxenda® first prescription date.
[3] Dysglycaemia, hypertension, dyslipidaemia, obstructive sleep apnoea and/or other weight-related comorbidities.
[4] Percentages based on the number of subjects with BMI $\geq$ 27 kg/m² and BMI < 30 kg/m².
[5] In patients with available BMI at treatment initiation.
[6] Measured 16-24 weeks after first prescription date.
[7] Based on last weight measurement observed within the index period.
[8] Considering only patients that completed at least 12 weeks of treatment.
[9] Considering only patients that completed at least 12 weeks of treatment. Based on last weight measurement during the period of 4-12 weeks after prescription date.
[10] Percentages based on number of subjects that completed at least 16 weeks of treatment. Based on last weight measurement before 16 weeks of treatment.
[11] Percentages based on number of subjects that completed more than 24 weeks of treatment. Based on last weight measurement after 24 weeks of treatment.

Table 14-12 Use of Saxenda® According to Approved Indication by Patient Age Group

	Saxenda® Analysis Set		
	Italy (N=75)		
	Patient Age Group (years)		
	<18-39 (N=8)	40-64 (N=48)	≥65 (N=19)
BMI and comorbidities			
BMI ≥ 30 kg/m² [1]	8 (100.0)	43 (89.6)	19 (100.0)
BMI ≥ 27 kg/m² and BMI < 30 kg/m² [1]	0 (0.0)	3 (6.3)	0 (0.0)
≥ 1 relevant comorbidity [2,3,4]	0	2 (66.7)	0
Dysglycaemia [4]	0	0 (0.0)	0
Hypertension [4]	0	0 (0.0)	0
Dyslipidaemia [4]	0	0 (0.0)	0
Obstructive sleep apnoea [4]	0	0 (0.0)	0
Other weight-related comorbidities [4]	0	2 (66.7)	0
No relevant comorbidity [2,3]	0	1 (33.3)	0
BMI < 27 kg/m² [1]	0 (0.0)	0 (0.0)	0 (0.0)
BMI not measured [1]	0 (0.0)	2 (4.2)	0 (0.0)
Stopping rule [5]			
Completed at least 16 weeks of treatment before index date	3 (37.5)	28 (58.3)	9 (47.4)
At least 5% weight loss and continuing treatment [6]	0 (0.0)	8 (28.6)	3 (33.3)
Less than 5% weight loss and continuing treatment [6]	0 (0.0)	2 (7.1)	0 (0.0)
Body measurements not taken between week 16 to 24	3 (100.0)	15 (53.6)	5 (55.6)

	Saxenda® Analysis Set		
Mean weight loss (%) [7] in patients not treated according to stopping rule			
N	0	2	0
Mean (SD)	-	-5.65 (4.738)	-
Median	-	-5.6	-
Min,Max	-	-9.0, -2.3	-
Q1,Q3	-	-9.0, -2.3	-
Missing	0	0	0
Number of patients that had at least 12 weeks of treatment	4 (50.0)	33 (68.8)	14 (73.7)
Number of non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date) [8]	1 (25.0)	12 (36.4)	6 (42.9)
Number of adherent patients (3.0 mg reached by 12 weeks after first prescription date) [8]	3 (75.0)	21 (63.6)	8 (57.1)
Number of patients with more than 5% weight loss at 4-12 weeks of treatment, n (%) [9]	1 (25.0)	9 (27.3)	7 (50.0)
Body measurements not taken between week 4 to 12 [8]	1 (12.5)	15 (31.3)	3 (15.8)
Mean weight loss at 12 weeks of treatment in patients that have not reached 3.0 mg Saxenda® dose at 12 weeks [9]			
N	1	9	6

	Saxenda® Analysis Set		
Mean (SD)	-5.00(-)	-4.72 (3.235)	-5.63 (2.425)
Median	-5.0	-4.2	-5.9
Min,Max	-5.0, -5.0	-11.0, -1.2	-8.8, -1.8
Q1,Q3	-5.0, -5.0	-6.7, -1.5	-7.0, -4.5
Missing	0	3	0
Mean weight loss at 12 weeks of treatment in patients that have reached 3.0 mg Saxenda® dose at 12 weeks [9]			
N	2	11	5
Mean (SD)	-5.75 (3.182)	-4.96 (2.341)	-5.76 (3.587)
Median	-5.8	-4.5	-5.3
Min,Max	-8.0, -3.5	-9.5, -1.5	-11.0, -1.0
Q1,Q3	-8.0, -3.5	-7.0, -3.5	-6.5, -5.0
Missing	1	10	3
Mean weight loss in patients that have not reached 3.0 mg Saxenda® dose at 12 weeks [7]			
N	1	11	6
Mean (SD)	-14.00(-)	-5.65 (5.581)	-9.73 (6.041)
Median	-14.0	-4.5	-9.7
Min,Max	-14.0, -14.0	-14.0, 4.0	-17.5, -1.8
Q1,Q3	-14.0, -14.0	-10.5, -2.2	-15.3, -4.5
Missing	0	1	0

	Saxenda® Analysis Set		
Mean weight loss in patients that have reached 3.0 mg Saxenda® dose at 12 weeks [7]			
N	2	18	7
Mean (SD)	-11.00 (4.243)	-11.32 (7.935)	-5.19 (3.387)
Median	-11.0	-8.8	-5.0
Min,Max	-14.0, -8.0	-33.0, -4.5	-11.0, -1.0
Q1,Q3	-14.0, -8.0	-13.6, -5.5	-8.0, -3.0
Missing	1	3	1
Mean weight loss in all patients [7]			
N	7	36	17
Mean (SD)	-6.53 (5.918)	-7.88 (7.344)	-7.89 (6.403)
Median	-6.5	-5.5	-5.3
Min,Max	-14.0, 0.0	-33.0, 4.0	-25.1, -1.0
Q1,Q3	-14.0, 0.0	-11.5, -4.0	-10.3, -3.0
Missing	1	12	2
Number of patients that completed at least 16 weeks of treatment, n (%)	3 (37.5)	28 (58.3)	9 (47.4)
Number of patients with more than 5% weight loss before 16 weeks of treatment, n (%) [10]	1 (33.3)	15 (53.6)	7 (77.8)
Body measurements not taken between first prescription to 16 weeks of treatment, n (%) [10]	0 (0.0)	9 (32.1)	1 (11.1)
Number of patients that had more than 24 weeks of treatment, n (%)	1 (12.5)	21 (43.8)	7 (36.8)

	Saxenda® Analysis Set		
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%) [11]	1 (100.0)	12 (57.1)	4 (57.1)
Body measurements not taken after 24 weeks of treatment, n (%) [11]	0 (0.0)	6 (28.6)	1 (14.3)
Number of patients that had more than 16 weeks of treatment and body measurements were not taken between week 16 to 24, n (%)	3 (37.5)	15 (31.3)	5 (26.3)
Number of patients with more than 5% weight loss before 16 weeks of treatment, n (%)	1 (33.3)	7 (46.7)	3 (60.0)
Number of patients with less than 5% weight loss before 16 weeks of treatment, n (%)	2 (66.7)	1 (6.7)	1 (20.0)
Number of patients that had more than 24 weeks of treatment, n (%)	1 (50.0)	0 (0.0)	1 (100.0)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%)	1 (100.0)	0	1 (100.0)
Body measurements not taken after 24 weeks of treatment, n (%)	0 (0.0)	0	0 (0.0)
Body measurements not taken between first prescription to 16 weeks of treatment, n (%)	0 (0.0)	7 (46.7)	1 (20.0)
Number of patients that had more than 24 weeks of treatment, n (%)	0	5 (71.4)	1 (100.0)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%)	0	4 (80.0)	0 (0.0)
Body measurements not taken after 24 weeks of treatment, n (%)	0	1 (20.0)	1 (100.0)
Number of patients that had more than 24 weeks of treatment and body measurements were not taken between week 16 to 24, n (%)	1 (12.5)	11 (22.9)	4 (21.1)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%)	1 (100.0)	7 (63.6)	1 (25.0)
Body measurements not taken after 24 weeks of treatment, n (%)	0 (0.0)	2 (18.2)	1 (25.0)

BMI: Body Mass Index. SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value.

[1] Within six months before date of first prescription.
[2] Before Saxenda® first prescription date.
[3] Dysglycaemia, hypertension, dyslipidaemia, obstructive sleep apnoea and/or other weight-related comorbidities.
[4] Percentages based on the number of subjects with BMI ≥ 27 kg/m² and BMI < 30 kg/m².
[5] In patients with available BMI at treatment initiation.
[6] Measured 16-24 weeks after first prescription date.
[7] Based on last weight measurement observed within the index period.
[8] Considering only patients that completed at least 12 weeks of treatment.
[9] Considering only patients that completed at least 12 weeks of treatment. Based on last weight measurement during the period of 4-12 weeks after prescription date.
[10] Percentages based on number of subjects that completed at least 16 weeks of treatment. Based on last weight measurement before 16 weeks of treatment.
[11] Percentages based on number of subjects that completed more than 24 weeks of treatment. Based on last weight measurement after 24 weeks of treatment.

Table 14-13 Use of Saxenda® According to Approved Indication by Body Mass Index at treatment initiation

	Saxenda® Analysis Set					
	Italy (N=75)					
	Body Mass Index categories (kg/m2)					
	<18.5 (N=0)	≥18.5-<25 (N=0)	≥25-<27 (N=0)	≥27-<30 (N=3)	≥30-<40 (N=40)	≥40 (N=30)
BMI and comorbidities						
BMI ≥ 30 kg/m² [1]	0	0	0	0 (0.0)	40 (100.0)	30 (100.0)
BMI ≥ 27 kg/m² and BMI < 30 kg/m² [1]	0	0	0	3 (100.0)	0 (0.0)	0 (0.0)
≥ 1 relevant comorbidity [2,3,4]	0	0	0	2 (66.7)	0	0
Dysglycaemia [4]	0	0	0	0 (0.0)	0	0
Hypertension [4]	0	0	0	0 (0.0)	0	0
Dyslipidaemia [4]	0	0	0	0 (0.0)	0	0
Obstructive sleep apnoea [4]	0	0	0	0 (0.0)	0	0
Other weight-related comorbidities [4]	0	0	0	2 (66.7)	0	0
No relevant comorbidity [2,3]	0	0	0	1 (33.3)	0	0
BMI < 27 kg/m² [1]	0	0	0	0 (0.0)	0 (0.0)	0 (0.0)
BMI not measured [1]	0	0	0	0 (0.0)	0 (0.0)	0 (0.0)
Stopping rule [5]						
At least 5% weight loss and continuing treatment [6]	0	0	0	0 (0.0)	6 (15.0)	5 (16.7)
Less than 5% weight loss and continuing treatment [6]	0	0	0	0 (0.0)	2 (5.0)	0 (0.0)
Body measurements not taken between week 16 to 24	0	0	0	3 (100.0)	30 (75.0)	22 (73.3)
Completed at least 16 weeks of treatment before index date	0	0	0	2 (66.7)	24 (60.0)	14 (46.7)

	Saxenda® Analysis Set					
Mean weight loss (%) [7] in patients not treated according to stopping rule						
N	0	0	0	0	2	0
Mean (SD)	-	-	-	-	-5.65 (4.738)	-
Median	-	-	-	-	-5.6	-
Min,Max	-	-	-	-	-9.0, -2.3	-
Q1,Q3	-	-	-	-	-9.0, -2.3	-
Missing	0	0	0	0	0	0
Number of patients that had at least 12 weeks of treatment	0	0	0	3 (100.0)	30 (75.0)	18 (60.0)
Number of non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date) [8]	0	0	0	0 (0.0)	11 (36.7)	8 (44.4)
Number of adherent patients (3.0 mg reached by 12 weeks after first prescription date) [8]	0	0	0	3 (100.0)	19 (63.3)	10 (55.6)
Number of patients with more than 5% weight loss at 4-12 weeks of treatment, n (%) [9]	0	0	0	1 (33.3)	10 (33.3)	6 (33.3)
Body measurements not taken between week 4 to 12 [8]	0	0	0	2 (66.7)	10 (25.0)	7 (23.3)
Mean weight loss at 12 weeks of treatment in patients that have not reached 3.0 mg Saxenda® dose at 12 weeks [9]						

				Saxenda® Analysis Set		
N	0	0	0	0	9	7
Mean (SD)	-	-	-	-	-3.89 (2.018)	-6.61 (3.009)
Median	-	-	-	-	-4.5	-7.0
Min,Max	-	-	-	-	-6.7, -1.2	-11.0, -1.8
Q1,Q3	-	-	-	-	-5.0, -1.5	-8.8, -4.0
Missing	0	0	0	0	2	1
Mean weight loss at 12 weeks of treatment in patients that have reached 3.0 mg Saxenda® dose at 12 weeks [9]						
N	0	0	0	1	11	6
Mean (SD)	-	-	-	-4.70(-)	-4.95 (2.226)	-5.97 (3.609)
Median	-	-	-	-4.7	-5.0	-6.2
Min,Max	-	-	-	-4.7, -4.7	-9.5, -1.0	-11.0, -1.5
Q1,Q3	-	-	-	-4.7, -4.7	-6.5, -3.5	-8.0, -3.0
Missing	0	0	0	2	8	4
Mean weight loss in patients that have not reached 3.0 mg Saxenda® dose at 12 weeks [7]						
N	0	0	0	0	10	8
Mean (SD)	-	-	-	-	-4.51 (5.073)	-11.17 (4.998)
Median	-	-	-	-	-3.9	-11.8
Min,Max	-	-	-	-	-14.0, 4.0	-17.5, -1.8
Q1,Q3	-	-	-	-	-9.0, -2.2	-14.7, -8.7
Missing	0	0	0	0	1	0

	Saxenda® Analysis Set					
Mean weight loss in patients that have reached 3.0 mg Saxenda dose at 12 weeks [7]						
N	0	0	0	2	16	9
Mean (SD)	-	-	-	-9.85 (7.283)	-7.71 (4.214)	-13.23 (10.339)
Median	-	-	-	-9.9	-6.5	-9.5
Min,Max	-	-	-	-15.0, -4.7	-15.0, -1.0	-33.0, -3.0
Q1,Q3	-	-	-	-15.0, -4.7	-11.5, -4.8	-13.6, -8.0
Missing	0	0	0	1	3	1
Mean weight loss in all patients [7]						
N	0	0	0	2	34	24
Mean (SD)	-	-	-	-9.85 (7.283)	-5.58 (4.557)	-10.59 (8.509)
Median	-	-	-	-9.9	-4.5	-8.8
Min,Max	-	-	-	-15.0, -4.7	-15.0, 4.0	-33.0, 0.0
Q1,Q3	-	-	-	-15.0, -4.7	-8.0, -3.0	-13.8, -5.0
Missing	0	0	0	1	6	6
Number of patients that completed at least 16 weeks of treatment, n (%)	0	0	0	2 (66.7)	24 (60.0)	14 (46.7)
Number of patients with more than 5% weight loss before 16 weeks of treatment, n (%) [10]	0	0	0	1 (50.0)	13 (54.2)	9 (64.3)
Body measurements not taken between first prescription to 16 weeks of treatment, n (%) [10]	0	0	0	1 (50.0)	7 (29.2)	2 (14.3)

	Saxenda® Analysis Set					
Number of patients that had more than 24 weeks of treatment, n (%)	0	0	0	1 (33.3)	18 (45.0)	10 (33.3)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%) [11]	0	0	0	1 (100.0)	10 (55.6)	6 (60.0)
Body measurements not taken after 24 weeks of treatment, n (%) [11]	0	0	0	0 (0.0)	4 (22.2)	3 (30.0)
Number of patients that had more than 16 weeks of treatment and body measurements were not taken between week 16 to 24, n (%)	0	0	0	2 (66.7)	14 (35.0)	7 (23.3)
Number of patients with more than 5% weight loss before 16 weeks of treatment, n (%)	0	0	0	1 (50.0)	6 (42.9)	4 (57.1)
Number of patients with less than 5% weight loss before 16 weeks of treatment, n (%)	0	0	0	0 (0.0)	3 (21.4)	1 (14.3)
Number of patients that had more than 24 weeks of treatment, n (%)	0	0	0	0	2 (66.7)	0 (0.0)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%)	0	0	0	0	2 (100.0)	0
Body measurements not taken after 24 weeks of treatment, n (%)	0	0	0	0	0 (0.0)	0
Body measurements not taken between first prescription to 16 weeks of treatment, n (%)	0	0	0	1 (50.0)	5 (35.7)	2 (28.6)
Number of patients that had more than 24 weeks of treatment, n (%)	0	0	0	0 (0.0)	4 (80.0)	2 (100.0)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%)	0	0	0	0	2 (50.0)	2 (100.0)
Body measurements not taken after 24 weeks of treatment, n (%)	0	0	0	0	2 (50.0)	0 (0.0)

	Saxenda® Analysis Set					
Number of patients that had more than 24 weeks of treatment and body measurements were not taken between week 16 to 24, n (%)	0	0	0	1 (33.3)	10 (25.0)	5 (16.7)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%)	0	0	0	1 (100.0)	5 (50.0)	3 (60.0)
Body measurements not taken after 24 weeks of treatment, n (%)	0	0	0	0 (0.0)	2 (20.0)	1 (20.0)

BMI: Body Mass Index. SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value.
[1] Within six months before date of first prescription. [2] Before Saxenda first prescription date.
[3] Dysglycaemia, hypertension, dyslipidaemia, obstructive sleep apnoea and/or other weight-related comorbidities.
[4] Percentages based on the number of subjects with BMI $\geq$ 27 kg/m² and BMI < 30 kg/m².
[5] In patients with available BMI at treatment initiation.
[6] Measured 16-24 weeks after first prescription date.
[7] Based on last weight measurement observed within the index period.
[8] Considering only patients that completed at least 12 weeks of treatment.
[9] Considering only patients that completed at least 12 weeks of treatment. Based on last weight measurement during the period of 4-12 weeks after prescription date.
[10] Percentages based on number of subjects that completed at least 16 weeks of treatment. Based on last weight measurement before 16 weeks of treatment.
[11] Percentages based on number of subjects that completed more than 24 weeks of treatment. Based on last weight measurement after 24 weeks of treatment.

Table 14-14 Use of Saxenda According to Approved Indication by Victoza Switch status before index date

	Saxenda Analysis Set	
	Italy (N=75)	
	Switched from Victoza	
	Yes (N=0)	No (N=75)
BMI and comorbidities		
BMI ≥ 30 kg/m² [1]	0	70 (93.3)
BMI ≥ 27 kg/m² and BMI < 30 kg/m² [1]	0	3 (4.0)
≥ 1 relevant comorbidity [2,3,4]	0	2 (66.7)
Dysglycaemia [4]	0	0 (0.0)
Hypertension [4]	0	0 (0.0)
Dyslipidaemia [4]	0	0 (0.0)
Obstructive sleep apnoea [4]	0	0 (0.0)
Other weight-related comorbidities [4]	0	2 (66.7)
No relevant comorbidity [2,3]	0	1 (33.3)
BMI < 27 kg/m² [1]	0	0 (0.0)
BMI not measured [1]	0	2 (2.7)
Stopping rule [5]		
Completed at least 16 weeks of treatment before index date	0	40 (53.3)
At least 5% weight loss and continuing treatment [6]	0	11 (27.5)
Less than 5% weight loss and continuing treatment [6]	0	2 (5.0)
Body measurements not taken between week 16 to 24	0	23 (57.5)

		Saxenda Analysis Set
Mean weight loss (%) [7] in patients not treated according to stopping rule		
N	0	2
Mean (SD)	-	-5.65 (4.738)
Median	-	-5.6
Min,Max	-	-9.0, -2.3
Q1,Q3	-	-9.0, -2.3
Missing	0	0
Number of patients that had at least 12 weeks of treatment	0	51 (68.0)
Number of non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date) [8]	0	19 (37.3)
Number of adherent patients (3.0 mg reached by 12 weeks after first prescription date) [8]	0	32 (62.7)
Number of patients with more than 5% weight loss at 4-12 weeks of treatment, n (%) [9]	0	17 (33.3)
Body measurements not taken between week 4 to 12 [8]	0	19 (25.3)
Mean weight loss at 12 weeks of treatment in patients that have not reached 3.0 mg Saxenda dose at 12 weeks [9]		
N	0	16
Mean (SD)	-	-5.08 (2.783)

		Saxenda Analysis Set
Median	-	-5.0
Min,Max	-	-11.0, -1.2
Q1,Q3	-	-6.9, -2.9
Missing	0	3
Mean weight loss at 12 weeks of treatment in patients that have reached 3.0 mg Saxenda dose at 12 weeks [9]		
N	0	18
Mean (SD)	-	-5.27 (2.647)
Median	-	-4.9
Min,Max	-	-11.0, -1.0
Q1,Q3	-	-7.0, -3.5
Missing	0	14
Mean weight loss in patients that have not reached 3.0 mg Saxenda dose at 12 weeks [7]		
N	0	18
Mean (SD)	-	-7.47 (5.960)
Median	-	-8.0
Min,Max	-	-17.5, 4.0
Q1,Q3	-	-13.0, -2.3
Missing	0	1
Mean weight loss in patients that have reached 3.0 mg Saxenda dose at 12		

		Saxenda Analysis Set
weeks [7]		
N	0	27
Mean (SD)	-	-9.71 (7.207)
Median	-	-8.0
Min,Max	-	-33.0, -1.0
Q1,Q3	-	-13.5, -5.0
Missing	0	5
Mean weight loss in all patients [7]		
N	0	60
Mean (SD)	-	-7.73 (6.846)
Median	-	-5.5
Min,Max	-	-33.0, 4.0
Q1,Q3	-	-11.0, -3.2
Missing	0	15
Number of patients that completed at least 16 weeks of treatment, n (%)	0	40 (53.3)
Number of patients with more than 5% weight loss before 16 weeks of treatment, n (%) [10]	0	23 (57.5)
Body measurements not taken between first prescription to 16 weeks of treatment, n (%) [10]	0	10 (25.0)
Number of patients that had more than 24 weeks of treatment, n (%)	0	29 (38.7)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n	0	17 (58.6)

	Saxenda Analysis Set	
(%) [11]		
Body measurements not taken after 24 weeks of treatment, n (%) [11]	0	7 (24.1)
Number of patients that had more than 16 weeks of treatment and body measurements were not taken between week 16 to 24, n (%)	0	23 (30.7)
Number of patients with more than 5% weight loss before 16 weeks of treatment, n (%)	0	11 (47.8)
Number of patients with less than 5% weight loss before 16 weeks of treatment, n (%)	0	4 (17.4)
Number of patients that had more than 24 weeks of treatment, n (%)	0	2 (50.0)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%)	0	2 (100.0)
Body measurements not taken after 24 weeks of treatment, n (%)	0	0 (0.0)
Body measurements not taken between first prescription to 16 weeks of treatment, n (%)	0	8 (34.8)
Number of patients that had more than 24 weeks of treatment, n (%)	0	6 (75.0)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%)	0	4 (66.7)
Body measurements not taken after 24 weeks of treatment, n (%)	0	2 (33.3)
Number of patients that had more than 24 weeks of treatment and body measurements were not taken between week 16 to 24, n (%)	0	16 (21.3)
Number of patients with more than 5% weight loss after 24 weeks of treatment, n (%)	0	9 (56.3)
Body measurements not taken after 24 weeks of treatment, n (%)	0	3 (18.8)

BMI: Body Mass Index. SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value.
[1] Within six months before date of first prescription.

[2] Before Saxenda first prescription date.
[3] Dysglycaemia, hypertension, dyslipidaemia, obstructive sleep apnoea and/or other weight-related comorbidities.
[4] Percentages based on the number of subjects with BMI ≥ 27 kg/m² and BMI < 30 kg/m².
[5] In patients with available BMI at treatment initiation.
[6] Measured 16-24 weeks after first prescription date.
[7] Based on last weight measurement observed within the index period.
[8] Considering only patients that completed at least 12 weeks of treatment.
[9] Considering only patients that completed at least 12 weeks of treatment. Based on last weight measurement during the period of 4-12 weeks after prescription date.
[10] Percentages based on number of subjects that completed at least 16 weeks of treatment. Based on last weight measurement before 16 weeks of treatment.
[11] Percentages based on number of subjects that completed more than 24 weeks of treatment. Based on last weight measurement after 24 weeks of treatment.
Note: 1 subject (Subject ID=[redacted]) switched to a [redacted]mg Saxenda dose from [redacted]mg Victoza dose on [redacted]. However, since the patient started Victoza during the Index period, it was considered in the Victoza Analysis Set and therefore it is not displayed in the tables which considers only Saxenda Analysis Set.

Table 14-15 Use of Victoza for Weight Management

	Victoza Analysis Set		
	Italy (N=75)	Germany (N=75)	Overall (N=150)
Number of patients with Victoza prescriptions fulfilling at least one of the following criteria	2 (2.7)	0 (0.0)	2 (1.3)
Dose information ≥3.0 mg per day	1 (1.3)	0 (0.0)	1 (0.7)
Indication of weight management without Type II diabetes [1]	1 (1.3)	0 (0.0)	1 (0.7)
Missing dose information [1]	1 (1.3)	0 (0.0)	1 (0.7)
Missing indication [1]	0 (0.0)	0 (0.0)	0 (0.0)

[1] At treatment initiation

Table 14-16 Use of Victoza for Weight Management by Patient Sex

	Victoza Analysis Set					
	Patient Sex					
	Male			Female		
	Italy (N=37)	Germany (N=40)	Overall (N=77)	Italy (N=38)	Germany (N=35)	Overall (N=73)
Number of patients with Victoza prescriptions fulfilling at least one of the following criteria	0 (0.0)	0 (0.0)	0 (0.0)	2 (5.3)	0 (0.0)	2 (2.7)
Dose information ≥3.0 mg per day	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	1 (1.4)
Indication of weight management without Type II diabetes [1]	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)	0 (0.0)	1 (1.4)
Missing dose information [1]	1 (2.7)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
Missing indication [1]	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

[1] At treatment initiation

Table 14-17 Use of Victoza for Weight Management by Patient Age Group

	Victoza Analysis Set								
	Patient Age Group								
	<18-39			40-64			≥65		
	Italy (N=2)	Germany (N=5)	Overall (N=7)	Italy (N=33)	Germany (N=47)	Overall (N=80)	Italy (N=40)	Germany (N=23)	Overall (N=63)
Number of patients with Victoza prescriptions fulfilling at least one of the following criteria	1 (50.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	1 (1.6)
Dose information ≥3.0 mg per day	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.5)	0 (0.0)	1 (1.6)
Indication of weight management without Type II diabetes [1]	1 (50.0)	0 (0.0)	1 (14.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Missing dose information [1]	0 (0.0)	0 (0.0)	0 (0.0)	1 (3.0)	0 (0.0)	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
Missing indication [1]	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

[1] At treatment initiation

Table 14-18 Use of Saxenda according to Approved Posology

	Saxenda Analysis Set
	Italy (N=75)
Concomitant medication with other GLP-1 receptor agonists	
Number of Saxenda patients with other GLP-1 receptor agonists prescribed during continued treatment with Saxenda [1]	0 (0.0)
Duration of treatment with Saxenda (months) [1]	
N	70
Mean (SD)	5.48 (4.300)
Median	4.0
Min,Max	0.4, 19.7
Q1,Q3	2.2, 8.2
Missing	5
Duration of treatment with Saxenda (months) – patients finished treatment at or before the index date [1]	
N	39
Mean (SD)	4.60 (3.090)
Median	4.2
Min,Max	0.6, 16.3
Q1,Q3	1.9, 6.5
Missing	4

	Saxenda Analysis Set
Duration of treatment with Saxenda (months) – patients with treatment ongoing at index date [1]	
N	31
Mean (SD)	6.60 (5.303)
Median	3.8
Min,Max	0.4, 19.7
Q1,Q3	2.2, 9.6
Missing	0
Duration of treatment with Saxenda - categorisation [1]	
0-6 months	44 (58.7)
7-12 months	20 (26.7)
13-18 months	4 (5.3)
19-24 months	2 (2.7)
Ongoing	31 (41.3)
Missing	5 (6.7)
Number of non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date) [2]	19 (30.6)
Number of patients that:	
Had at least 12 weeks of treatment	51 (68.0)
Are non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date)	32 (42.7)
Are adherent patients (3.0 mg not reached by 12 weeks after first prescription date)	43 (57.3)

	Saxenda Analysis Set
Reached 3.0 mg Saxenda dose at any time during follow-up	49 (65.3)
Do not have any reported dose change during 4-12 weeks after first prescription date	46 (61.3)

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value

[1] Treatment duration is defined as: (Index date – Treatment initiation date + 1)/30.44 for patients continuing the treatment at index date and (last dose of treatment date – Treatment initiation date)/30.44 for patients discontinuing treatment during study period.

Index is defined as 24 months after launch of Saxenda in the country.

[2] Total number of patients considered for the denominator (N=62) includes only patients which, at index date, have completed at least 12 weeks of treatment or have reached 3.0 mg even though they have not completed 12 weeks of treatment. Patients which at index date have not completed 12 weeks of treatment and have not reached 3.0 mg dose were excluded from this calculation.

Table 14-19 Use of Saxenda according to Approved Posology by Patient Sex

	Saxenda Analysis Set	
	Italy (N=75)	
	Patient Gender	
	Male (N=27)	Female (N=48)
Concomitant medication with other GLP-1 receptor agonists		
Number of Saxenda patients with other GLP-1 receptor agonists prescribed during continued treatment with Saxenda [1]	0 (0.0)	0 (0.0)
Duration of treatment with Saxenda (months) [1]		
N	25	45
Mean (SD)	5.39 (4.908)	5.54 (3.981)
Median	3.6	4.6
Min,Max	0.6, 19.7	0.4, 19.0
Q1,Q3	2.2, 6.5	2.6, 8.2
Missing	2	3
Duration of treatment with Saxenda (months) – patients finished treatment at or before the index date [1]		
N	15	24
Mean (SD)	3.11 (1.675)	5.53 (3.422)
Median	3.0	5.3
Min,Max	0.6, 6.5	1.3, 16.3
Q1,Q3	1.8, 4.2	2.7, 7.5

	Saxenda Analysis Set	
Missing	1	3
Duration of treatment with Saxenda (months) – patients with treatment ongoing at index date [1]		
N	10	21
Mean (SD)	8.80 (6.182)	5.55 (4.625)
Median	9.5	3.6
Min,Max	0.7, 19.7	0.4, 19.0
Q1,Q3	3.4, 13.4	1.7, 8.8
Missing	0	0
Duration of treatment with Saxenda - categorisation [1]		
0-6 months	18 (66.7)	26 (54.2)
7-12 months	3 (11.1)	17 (35.4)
13-18 months	3 (11.1)	1 (2.1)
19-24 months	1 (3.7)	1 (2.1)
Ongoing	10 (37.0)	21 (43.8)
Missing	2 (7.4)	3 (6.3)
Number of non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date) [2]	3 (13.6)	16 (40.0)
Number of patients that:		
Had at least 12 weeks of treatment	16 (59.3)	35 (72.9)

	Saxenda Analysis Set	
Are non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date)	8 (29.6)	24 (50.0)
Are adherent patients (3.0 mg not reached by 12 weeks after first prescription date)	19 (70.4)	24 (50.0)
Reached 3.0 mg Saxenda dose at any time during follow-up	21 (77.8)	28 (58.3)
Do not have any reported dose change during 4-12 weeks after first prescription date	17 (63.0)	29 (60.4)

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value

[1] Treatment duration is defined as: (Index date – Treatment initiation date + 1)/30.44 for patients continuing the treatment at index date and (last dose of treatment date – Treatment initiation date)/30.44 for patients discontinuing treatment during study period.

Index is defined as 24 months after launch of Saxenda in the country.

[2] Total number of patients considered for the denominator (N=62) includes only patients which, at index date, have completed at least 12 weeks of treatment or have reached 3.0 mg even though they have not completed 12 weeks of treatment. Patients which at index date have not completed 12 weeks of treatment and have not reached 3.0 mg dose were excluded from this calculation.

Table 14-20 Use of Saxenda according to Approved Posology by Patient Age Group

	Saxenda Analysis Set		
	Italy (N=75)		
	Patient Age Group (years)		
	<18-39 (N=8)	40-64 (N=48)	≥65 (N=19)
Concomitant medication with other GLP-1 receptor agonists			
Number of Saxenda patients with other GLP-1 receptor agonists prescribed during continued treatment with Saxenda [1]	0 (0.0)	0 (0.0)	0 (0.0)
Duration of treatment with Saxenda (months) [1]			
N	7	44	19
Mean (SD)	4.64 (5.285)	5.44 (3.993)	5.90 (4.796)
Median	3.6	4.5	3.6
Min,Max	0.6, 16.3	0.4, 19.0	0.6, 19.7
Q1,Q3	1.5, 4.2	2.0, 8.2	2.6, 9.0
Missing	1	4	0
Duration of treatment with Saxenda (months) – patients finished treatment at or before the index date [1]			
N	5	24	10
Mean (SD)	5.44 (6.198)	4.44 (2.396)	4.55 (2.846)
Median	3.6	4.2	3.8
Min,Max	0.6, 16.3	1.1, 9.0	1.6, 9.0
Q1,Q3	2.6, 4.2	2.3, 6.5	1.9, 7.1

	Saxenda Analysis Set		
Missing	1	3	0
Duration of treatment with Saxenda (months) – patients with treatment ongoing at index date [1]			
N	2	20	9
Mean (SD)	2.63 (1.626)	6.64 (5.135)	7.40 (6.151)
Median	2.6	8.0	3.6
Min,Max	1.5, 3.8	0.4, 19.0	0.6, 19.7
Q1,Q3	1.5, 3.8	2.0, 9.2	3.4, 10.4
Missing	0	0	0
Duration of treatment with Saxenda - categorisation [1]			
0-6 months	6 (75.0)	26 (54.2)	12 (63.2)
7-12 months	0 (0.0)	15 (31.3)	5 (26.3)
13-18 months	1 (12.5)	2 (4.2)	1 (5.3)
19-24 months	0 (0.0)	1 (2.1)	1 (5.3)
Ongoing	2 (25.0)	20 (41.7)	9 (47.4)
Missing	1 (12.5)	4 (8.3)	0 (0.0)
Number of non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date) [2]	1 (14.3)	12 (31.6)	6 (35.3)
Number of patients that:			
Had at least 12 weeks of treatment	4 (50.0)	33 (68.8)	14 (73.7)

	Saxenda Analysis Set		
Are non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date)	2 (25.0)	22 (45.8)	8 (42.1)
Are adherent patients (3.0 mg not reached by 12 weeks after first prescription date)	6 (75.0)	26 (54.2)	11 (57.9)
Reached 3.0 mg Saxenda dose at any time during follow-up	6 (75.0)	29 (60.4)	14 (73.7)
Do not have any reported dose change during 4-12 weeks after first prescription date	5 (62.5)	30 (62.5)	11 (57.9)

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value

[1] Treatment duration is defined as: (Index date – Treatment initiation date + 1)/30.44 for patients continuing the treatment at index date and (last dose of treatment date – Treatment initiation date)/30.44 for patients discontinuing treatment during study period.

Index is defined as 24 months after launch of Saxenda in the country.

[2] Total number of patients considered for the denominator (N=62) includes only patients which, at index date, have completed at least 12 weeks of treatment or have reached 3.0 mg even though they have not completed 12 weeks of treatment. Patients which at index date have not completed 12 weeks of treatment and have not reached 3.0 mg dose were excluded from this calculation.

Table 14-21 Use of Saxenda according to Approved Posology by Body Mass Index at treatment initiation

	Saxenda Analysis Set					
	Italy (N=75)					
	Body Mass Index categories (kg/m2)					
	<18.5 (N=0)	≥18.5-<25 (N=0)	≥25-<27 (N=0)	≥27-<30 (N=3)	≥30-<40 (N=40)	≥40 (N=30)
Concomitant medication with other GLP-1 receptor agonists						
Number of Saxenda patients with other GLP-1 receptor agonists prescribed during continued treatment with Saxenda [1]	0	0	0	0 (0.0)	0 (0.0)	0 (0.0)
Duration of treatment with Saxenda (months) [1]						
N	0	0	0	3	36	30
Mean (SD)	-	-	-	5.89 (3.373)	5.99 (4.290)	5.01 (4.421)
Median	-	-	-	5.2	4.5	3.6
Min,Max	-	-	-	2.9, 9.6	0.7, 19.0	0.6, 19.7
Q1,Q3	-	-	-	2.9, 9.6	3.0, 8.6	1.7, 6.5
Missing	0	0	0	0	4	0
Duration of treatment with Saxenda (months) – patients finished treatment at or before the index date [1]						
N	0	0	0	1	20	18
Mean (SD)	-	-	-	5.19(-)	4.81 (3.556)	4.33 (2.656)
Median	-	-	-	5.2	4.0	3.9

	Saxenda Analysis Set					
Min,Max	-	-	-	5.2, 5.2	1.1, 16.3	0.6, 9.0
Q1,Q3	-	-	-	5.2, 5.2	2.3, 6.9	1.9, 6.4
Missing	0	0	0	0	4	0
Duration of treatment with Saxenda (months) – patients with treatment ongoing at index date [1]						
N	0	0	0	2	16	12
Mean (SD)	-	-	-	6.24 (4.692)	7.46 (4.768)	6.02 (6.226)
Median	-	-	-	6.2	8.3	3.6
Min,Max	-	-	-	2.9, 9.6	0.7, 19.0	0.6, 19.7
Q1,Q3	-	-	-	2.9, 9.6	3.2, 9.5	1.6, 10.8
Missing	0	0	0	0	0	0
Duration of treatment with Saxenda - categorisation [1]						
0-6 months	0	0	0	2 (66.7)	20 (50.0)	21 (70.0)
7-12 months	0	0	0	1 (33.3)	13 (32.5)	6 (20.0)
13-18 months	0	0	0	0 (0.0)	2 (5.0)	2 (6.7)
19-24 months	0	0	0	0 (0.0)	1 (2.5)	1 (3.3)
Ongoing	0	0	0	2 (66.7)	16 (40.0)	12 (40.0)
Missing	0	0	0	0 (0.0)	4 (10.0)	0 (0.0)
Number of non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date) [2]	0	0	0	0 (0.0)	11 (31.4)	8 (33.3)

	Saxenda Analysis Set					
Number of patients that:						
Had at least 12 weeks of treatment	0	0	0	3 (100.0)	30 (75.0)	18 (60.0)
Are non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date)	0	0	0	0 (0.0)	16 (40.0)	14 (46.7)
Are adherent patients (3.0 mg not reached by 12 weeks after first prescription date)	0	0	0	3 (100.0)	24 (60.0)	16 (53.3)
Reached 3.0 mg Saxenda dose at any time during follow-up	0	0	0	3 (100.0)	28 (70.0)	18 (60.0)
Do not have any reported dose change during 4-12 weeks after first prescription date	0	0	0	3 (100.0)	23 (57.5)	18 (60.0)

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value

[1] Treatment duration is defined as: (Index date – Treatment initiation date + 1)/30.44 for patients continuing the treatment at index date and (last dose of treatment date – Treatment initiation date)/30.44 for patients discontinuing treatment during study period.

Index is defined as 24 months after launch of Saxenda in the country.

[2] Total number of patients considered for the denominator (N=62) includes only patients which, at index date, have completed at least 12 weeks of treatment or have reached 3.0 mg even though they have not completed 12 weeks of treatment. Patients which at index date have not completed 12 weeks of treatment and have not reached 3.0 mg dose were excluded from this calculation.

Table 14-22 Use of Saxenda according to Approved Posology by Victoza Switch status

	Saxenda Analysis Set	
	Italy (N=75)	
	Switched from Victoza	
	Yes (N=0)	No (N=75)
Concomitant medication with other GLP-1 receptor agonists		
Number of Saxenda patients with other GLP-1 receptor agonists prescribed during continued treatment with Saxenda [1]	0	0 (0.0)
Duration of treatment with Saxenda (months) [1]		
N	0	70
Mean (SD)	-	5.48 (4.300)
Median	-	4.0
Min,Max	-	0.4, 19.7
Q1,Q3	-	2.2, 8.2
Missing	0	5
Duration of treatment with Saxenda (months) – patients finished treatment at or before the index date [1]		
N	0	39
Mean (SD)	-	4.60 (3.090)
Median	-	4.2
Min,Max	-	0.6, 16.3
Q1,Q3	-	1.9, 6.5

		Saxenda Analysis Set
Missing	0	4
Duration of treatment with Saxenda (months) – patients with treatment ongoing at index date [1]		
N	0	31
Mean (SD)	-	6.60 (5.303)
Median	-	3.8
Min,Max	-	0.4, 19.7
Q1,Q3	-	2.2, 9.6
Missing	0	0
Duration of treatment with Saxenda - categorisation [1]		
0-6 months	0	44 (58.7)
7-12 months	0	20 (26.7)
13-18 months	0	4 (5.3)
19-24 months	0	2 (2.7)
Ongoing	0	31 (41.3)
Missing	0	5 (6.7)
Number of non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date) [2]	0	19 (30.6)
Number of patients that:		
Had at least 12 weeks of treatment	0	51 (68.0)

		Saxenda Analysis Set
Are non-adherent patients (3.0 mg not reached by 12 weeks after first prescription date)	0	32 (42.7)
Are adherent patients (3.0 mg not reached by 12 weeks after first prescription date)	0	43 (57.3)
Reached 3.0 mg Saxenda dose at any time during follow-up	0	49 (65.3)
Do not have any reported dose change during 4-12 weeks after first prescription date	0	46 (61.3)

SD: Standard Deviation. Q1: First Quartile. Q3: Third Quartile. Min: Minimum value. Max: Maximum value
[1] Treatment duration is defined as: (Index date – Treatment initiation date + 1)/30.44 for patients continuing the treatment at index date and (last dose of treatment date – Treatment initiation date)/30.44 for patients discontinuing treatment during study period.
Index is defined as 24 months after launch of Saxenda in the country.
[2] Total number of patients considered for the denominator (N=62) includes only patients which, at index date, have completed at least 12 weeks of treatment or have reached 3.0mg even though they have not completed 12 weeks of treatment. Patients which at index date have not completed 12 weeks of treatment and have not reached 3.0mg dose were excluded from this calculation.
Note: 1 subject (Subject ID=[redacted]) switched to a [redacted] mg Saxenda dose from [redacted] mg Victoza dose on [redacted]. However, since the patient started Victoza during the Index period, it was considered in the Victoza Analysis Set and therefore it is not displayed in the tables which considers only Saxenda Analysis Set.

Table 14-23 Victoza prescription information

	Victoza Analysis Set		
	Italy (N=75)	Germany (N=75)	Overall (N=150)
Victoza indication prescribed, n (%)			
Type II Diabetes	74(98.7)	75(100.0)	149(99.3)
Other	1(1.3)	0(0.0)	1(0.7)
Victoza dose at initial prescription, n (%)			
0.6 mg	62(82.7)	63(84.0)	125(83.3)
1.2 mg	11(14.7)	9(12.0)	20(13.3)
1.8 mg	1(1.3)	1(1.3)	2(1.3)
Other	0(0.0)	2(2.7)	2(1.3)
Number of Victoza dose changes, n (%)			
0	10(13.3)	14(18.7)	24(16.0)
1	36(48.0)	45(60.0)	81(54.0)
2	25(33.3)	12(16.0)	37(24.7)
>2	4(5.3)	4(5.3)	8(5.3)
Number of patients with at least one prescription with dose information ≥3 mg/day, n (%)	1(1.3)	0(0.0)	1(0.7)
Final Victoza dose reached, n (%)			
0.6 mg/day	4(5.3)	12(16.0)	16(10.7)

	Victoza Analysis Set		
1.2 mg/day	44(58.7)	49(65.3)	93(62.0)
1.8 mg/day	25(33.3)	14(18.7)	39(26.0)
>=3 mg/day	1(1.3)	0(0.0)	1(0.7)

Table 14-24 Saxenda prescription information

	Saxenda Analysis Set
	Italy (N=75)
Saxenda indication prescribed, n (%)	
BMI ≥ 30 kg/m² (obese)	71 (94.7)
≥ 27 kg/m² to < 30 kg/m² (overweight) in the presence of at least one weight-related comorbidity	3 (4.0)
Other	1 (1.3)
Victoza to Saxenda switch n (%) [1]	0 (0.0)
Last Victoza dose before switch, n (%) [2]	
0.6 mg	0
1.2 mg	0
1.8 mg	0
Other	0
Missing	0
Saxenda dose at initial prescription, n (%)	
0.6 mg	70 (93.3)
1.2 mg	2 (2.7)
1.8 mg	2 (2.7)
2.4 mg	0 (0.0)
3.0 mg	1 (1.3)

	Saxenda Analysis Set
Other	0 (0.0)
Missing	0 (0.0)
Saxenda dose at 0-4 weeks, n (%)	
0.6 mg	0 (0.0)
1.2 mg	11 (14.7)
1.8 mg	13 (17.3)
2.4 mg	7 (9.3)
3.0 mg	35 (46.7)
Other	0 (0.0)
Missing	9 (12.0)
Discontinued Saxenda before week 4	6 (8.0)
Saxenda dose at 4-12 weeks, n (%)	
0.6 mg	1 (1.3)
1.2 mg	3 (4.0)
1.8 mg	5 (6.7)
2.4 mg	5 (6.7)
3.0 mg	14 (18.7)
Other	1 (1.3)
Missing	46 (61.3)
Discontinued Saxenda before week 12	23 (30.7)

	Saxenda Analysis Set
Saxenda dose at 12-24 weeks, n (%)	
0.6 mg	0 (0.0)
1.2 mg	0 (0.0)
1.8 mg	2 (2.7)
2.4 mg	3 (4.0)
3.0 mg	8 (10.7)
Other	0 (0.0)
Missing	62 (82.7)
Discontinued Saxenda before week 24	45 (60.0)
Number of Saxenda dose changes, n (%)	
0	1 (1.3)
1	10 (13.3)
2	9 (12.0)
>2	55 (73.3)
Final Saxenda dose of 3.0 mg/day, n (%) [3], n (%)	45 (72.6)

BMI: Body Mass Index.
[1] 1 subject (Subject ID=[redacted]) switched to a [redacted] mg Saxenda dose from [redacted] mg Victoza dose on [redacted]. However, since the patient started Victoza during the Index period, it was considered in the Victoza Analysis Set and therefore it is not displayed in the tables which considers only Saxenda Analysis Set.
[2] Percentage calculated among patients switched from Victoza
[3] Total number of patients considered for the denominator (N=xx) includes only patients which, at index date, have completed at least 12 weeks of treatment or have reached 3.0mg even though they have not completed 12 weeks of treatment. Patients which at index date have not completed 12 weeks of treatment and have not reached 3.0mg dose were excluded from this calculation.

Figure 14-1 Patient BMI at Saxenda treatment initiation

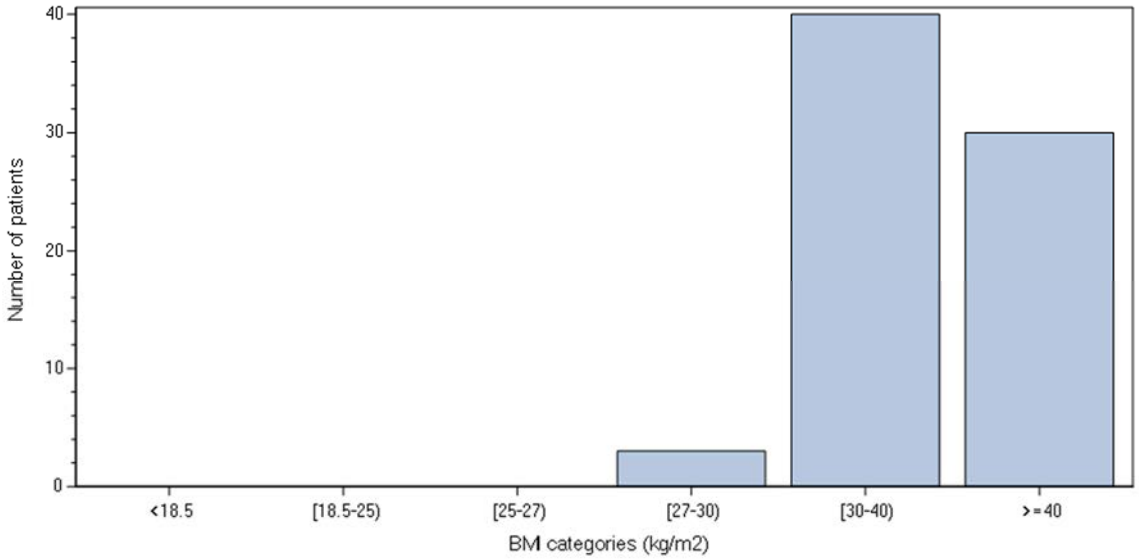
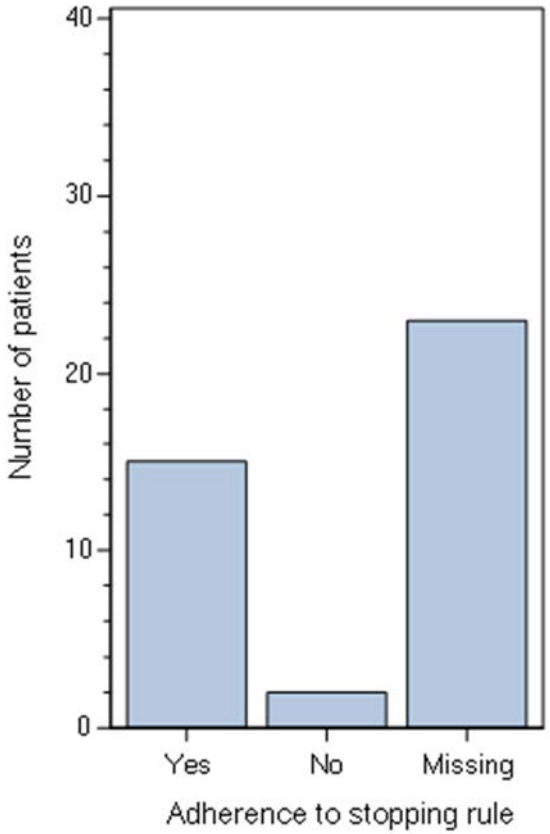
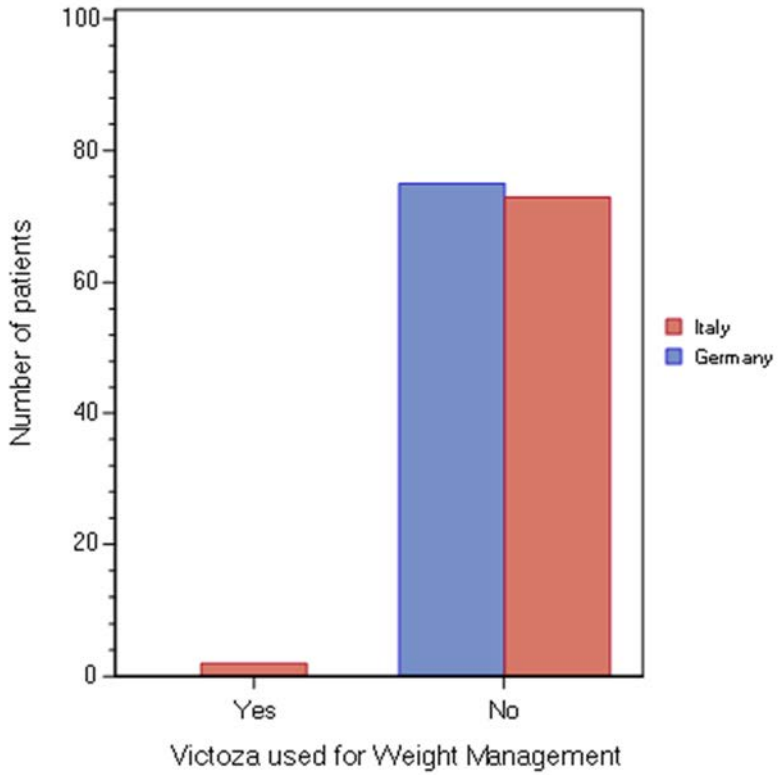


Figure 14-2 Saxenda use according to stopping rule



Note: Only includes patients that completed at least 16 weeks of treatment
Note 2: Missing category includes patients for which body measurements were not taken between week 16 to 24. Additional information is available at Table 10-16.

Figure 14-3 Victoza use for weight management



Victoza use for weight management is defined as having a prescription with:

- Dose information ≥3.0 mg per day, or;
- Indication of weight management, and type 2 diabetes not part of indication

Listing 1.1 Site characteristics - participating sites

Country	Region	Site ID	Practice type	Physician primary specialty	Physician secondary specialty	Rural/Urban classification	Number of physicians	Patient volume	Number of patients prescribed Saxenda	Number of patients prescribed Victoza
Italy	[redacted]					Urban	5	35	2	33
Italy						Rural	1	60	60	0
Italy						Rural	1	10	0	10
Italy						Urban	2	162	6	156
Italy						Urban	4	25	20	5
Italy						Urban	5	288	8	280

Country	Region	Site ID	Practice type	Physician primary specialty	Physician secondary specialty	Rural/Urban classification	Number of physicians	Patient volume	Number of patients prescribed Saxenda	Number of patients prescribed Victoza
Italy	[redacted]					Urban	2	17	7	10
Italy						Urban	8	70	20	50
Italy						Urban	30	130	30	100
Italy						Urban	6	47	14	33
Italy						Urban	2	11	1	10
Italy						Urban	1	33	33	0
Italy						Rural	50	150	0	150
Italy						Rural	1	6	0	6

Country	Region	Site ID	Practice type	Physician primary specialty	Physician secondary specialty	Rural/Urban classification	Number of physicians	Patient volume	Number of patients prescribed Saxenda	Number of patients prescribed Victoza
Italy	[redacted]					Urban	3	30	0	30
Italy						Urban	50	6	5	1
Italy						Rural	3	10	10	0
Italy						Urban	5	300	40	260
Italy						Rural	2	210	10	200
Italy						Rural	4	45	0	45
Italy						Rural	2	4	0	4

Country	Region	Site ID	Practice type	Physician primary specialty	Physician secondary specialty	Rural/Urban classification	Number of physicians	Patient volume	Number of patients prescribed Saxenda	Number of patients prescribed Victoza
Italy	[redacted]					Rural	8	4	2	2
Italy						Urban	2	37	0	37
Italy						Urban	4	40	0	40
Italy						Urban	1	4	0	4
Germany						Urban	2	4	NA	4
Germany						Urban	38	110	NA	110
Germany						Urban	1	15	NA	15

Country	Region	Site ID	Practice type	Physician primary specialty	Physician secondary specialty	Rural/Urban classification	Number of physicians	Patient volume	Number of patients prescribed Saxenda	Number of patients prescribed Victoza
Germany	[redacted]					Urban	1	200	NA	200
Germany						Rural	1	6	NA	6
Germany						Urban	6	120	NA	120
Germany						Rural	2	38	NA	38
Germany						Rural	2	47	NA	47
Germany						Rural	1	20	NA	20
Germany						Urban	1	50	NA	50

Country	Region	Site ID	Practice type	Physician primary specialty	Physician secondary specialty	Rural/Urban classification	Number of physicians	Patient volume	Number of patients prescribed Saxenda	Number of patients prescribed Victoza
Germany	[redacted]					Urban	2	59	NA	59
Germany						Rural	3	100	NA	100
Germany						Rural	3	55	NA	55
Germany						Urban	8	170	NA	170
Germany						Urban	5	46	NA	46
Germany						Urban	3	180	NA	180

Listing 1.2 Site characteristics - non-participating sites

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]			Not Interested
Italy				Not Interested
Germany				Missing
Germany				Not Interested
Germany				Not Interested
Germany				Lack of Subject Population
Italy				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]			Missing
Germany				Missing
Italy				Missing
Germany				Lack of Staff/Resources
Germany				Not Interested
Germany				No Time/Not Taking Studies
Italy				Missing
Germany				Missing
Germany				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]			Missing
Germany				Not Interested
Italy				No Conduct of this Study Type
Germany				Missing
Germany				Missing
Germany				Missing
Germany				Missing
Germany				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]			Not Interested
Italy				Not Interested
Germany				Lack of Staff/Resources
Italy				Missing
Germany				Not Interested
Germany				Missing
Germany				Missing
Italy				Lack of Subject Population
Germany				Not Interested

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]			Not Interested
Germany				Not Interested
Germany				Missing
Germany				Missing
Germany				Missing
Germany				Not Interested
Italy				Missing
Germany				Lack of Staff/Resources

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]		[redacted]	Lack of Subject Population
Italy				PI No Longer At Site
Italy				Missing
Germany				Missing
Germany				Not Interested
Germany				Not Interested
Germany				Not Interested
Germany				Not Interested
Germany				PI Retired

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]	[redacted]	[redacted]	Missing
Italy				Missing
Italy				Not Interested
Germany				Missing
Italy				Missing
Italy				Missing
Italy				Missing
Italy				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]		[redacted]	Missing
Italy				Lack of Subject Population
Italy				Missing
Italy				Not Interested
Germany				Not Interested
Italy				Missing
Italy				Missing
Italy				Missing
Italy				Lack of Staff/Resources

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]		[redacted]	Not Interested
Italy				Missing
Italy				Replacement PI
Italy				Not Interested
Italy				No Time/Not Taking Studies
Italy				Lack of Staff/Resources
Germany				Missing
Italy				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]		[redacted]	Missing
Italy				Missing
Italy				Not Interested
Germany				Lack of Subject Population
Germany				Not Interested
Germany				Missing
Italy				Missing
Germany				Missing
Italy				No Time/Not Taking Studies

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]	[redacted]	[redacted]	Missing
Germany	[redacted]	[redacted]	[redacted]	Missing
Germany	[redacted]	[redacted]	[redacted]	No Longer Doing Research
Germany	[redacted]	[redacted]	[redacted]	Lack of Subject Population
Germany	[redacted]	[redacted]	[redacted]	Missing
Italy	[redacted]	[redacted]	[redacted]	Missing
Italy	[redacted]	[redacted]	[redacted]	Not Interested
Italy	[redacted]	[redacted]	[redacted]	Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]	[redacted]	[redacted]	Missing
Italy				Lack of Subject Population
Italy				Missing
Italy				Missing
Italy				Missing
Germany				No Conduct of this Study Type
Germany				Not Interested
Germany				Lack of Staff/Resources
Italy				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]		[redacted]	Missing
Germany				Competing Studies
Germany				Missing
Germany				Missing
Germany				Missing
Italy				Missing
Germany				Missing
Germany				Lack of Subject Population

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]		[redacted]	No Time/Not Taking Studies
Italy				Missing
Germany				Missing
Germany				Missing
Italy				Missing
Germany				Missing
Germany				No Conduct of this Study Type
Germany				Missing
Italy				Not Interested

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]	[redacted]	[redacted]	Missing
Italy	[redacted]	[redacted]	[redacted]	Missing
Germany	[redacted]	[redacted]	[redacted]	Lack of Subject Population
Germany	[redacted]	[redacted]	[redacted]	No Time/Not Taking Studies
Italy	[redacted]	[redacted]	[redacted]	Missing
Germany	[redacted]	[redacted]	[redacted]	Not Interested
Germany	[redacted]	[redacted]	[redacted]	Missing
Germany	[redacted]	[redacted]	[redacted]	Lack of Staff/Resources

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]		[redacted]	Lack of Subject Population
Germany				Not Interested
Italy				Not Interested
Germany				No Time/Not Taking Studies
Germany				No Time/Not Taking Studies
Italy				Missing
Italy				Missing
Germany				Missing
Germany				No Time/Not Taking Studies

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]		[redacted]	No Longer Doing Research
Germany				Not Interested
Germany				Not Interested
Italy				No Conduct of this Study Type
Italy				Missing
Germany				Missing
Germany				PI Retired
Germany				Not Interested

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]		[redacted]	Missing
Italy				Competing Studies
Germany				Missing
Italy				Missing
Germany				Missing
Germany				Not Interested
Italy				Not Interested
Italy				Missing
Italy				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]		[redacted]	Missing
Italy				Missing
Germany				No Time/Not Taking Studies
Germany				Missing
Germany				Missing
Italy				Missing
Italy				No Time/Not Taking Studies
Italy				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]		[redacted]	Lack of Subject Population
Italy				Missing
Germany				Long Ethics/RA Timelines
Germany				Not Interested
Germany				Lack of Subject Population
Germany				PI Retired
Germany				Not Interested
Germany				Missing
Germany				No Time/Not Taking Studies

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]		[redacted]	Not Interested
Germany				Missing
Germany				Not Interested
Germany				Missing
Germany				Not Interested
Germany				Missing
Germany				No Time/Not Taking Studies
Germany				Not Interested

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]		[redacted]	Lack of Staff/Resources
Italy				Missing
Germany				Not Interested
Germany				Missing
Germany				No Longer Doing Research
Germany				Missing
Germany				Lack of Subject Population
Germany				Missing
Germany				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]		[redacted]	No Conduct of this Study Type
Germany				Lack of Subject Population
Germany				Not Interested
Germany				Lack of Subject Population
Germany				Lack of Staff/Resources
Germany				Not Interested
Germany				Missing
Germany				Study Design

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]		[redacted]	PI Retired
Germany				Not Interested
Germany				Missing
Germany				Not Interested
Germany				No Conduct of this Study Type
Germany				Missing
Italy				Missing
Italy				Not Interested
Germany				No Longer Doing Research

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]		[redacted]	No Time/Not Taking Studies
Italy				Lack of Subject Population
Italy				No Time/Not Taking Studies
Germany				Missing
Germany				Not Interested
Germany				Missing
Italy				No Conduct of this Study Type
Italy				Not Interested

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]		[redacted]	Missing
Germany				No Time/Not Taking Studies
Germany				Missing
Germany				Missing
Italy				Missing
Italy				Missing
Italy				Missing
Germany				No Time/Not Taking Studies
Germany				Not Interested

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]		[redacted]	No Time/Not Taking Studies
Italy				Missing
Germany				Missing
Italy				No Time/Not Taking Studies
Italy				Missing
Italy				Missing
Italy				Not Interested
Italy				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]		[redacted]	Not Interested
Italy				No Longer Doing Research
Germany				Missing
Germany				Not Interested
Germany				Not Interested
Italy				Not Interested
Italy				No Time/Not Taking Studies
Italy				Missing
Germany				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]		[redacted]	No Time/Not Taking Studies
Germany				Missing
Italy				Missing
Germany				Missing
Germany				No Conduct of this Study Type
Italy				Not Interested
Italy				Missing
Italy				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]		[redacted]	Missing
Germany				Missing
Italy				Lack of Staff/Resources
Germany				Missing
Germany				Not Interested
Germany				No Time/Not Taking Studies
Germany				PI No Longer At Site
Italy				Missing
Germany				Lack of Staff/Resources

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]	[redacted]	[redacted]	Missing
Germany				No Time/Not Taking Studies
Italy				Missing
Italy				Missing
Italy				Missing
Germany				Lack of Subject Population
Italy				Missing
Italy				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]		[redacted]	Missing
Italy				Missing
Germany				Not Interested
Germany				Missing
Italy				Missing
Italy				Missing
Germany				Missing
Italy				Missing
Italy				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]	[redacted]	[redacted]	Missing
Germany	[redacted]	[redacted]	[redacted]	Missing
Germany	[redacted]	[redacted]	[redacted]	Missing
Germany	[redacted]	[redacted]	[redacted]	Missing
Germany	[redacted]	[redacted]	[redacted]	Not Interested
Italy	[redacted]	[redacted]	[redacted]	Missing
Italy	[redacted]	[redacted]	[redacted]	Lack of Subject Population
Italy	[redacted]	[redacted]	[redacted]	Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]	[redacted]	[redacted]	Missing
Italy				Missing
Germany				Not Interested
Italy				Missing
Italy				Missing
Germany				Missing
Germany				Missing
Germany				Missing
Germany				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]		[redacted]	Missing
Germany				Not Interested
Italy				Not Interested
Italy				Missing
Italy				Missing
Germany				Missing
Italy				Missing
Italy				Not Interested

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]		[redacted]	Missing
Germany				Not Interested
Germany				Missing
Germany				Missing
Germany				Missing
Germany				Not Interested
Italy				Missing
Italy				No Time/Not Taking Studies
Italy				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]		[redacted]	Missing
Germany				No Time/Not Taking Studies
Germany				No Conduct of this Study Type
Germany				Lack of Staff/Resources
Germany				Missing
Germany				No Longer Doing Research
Germany				Not Interested
Germany				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]		[redacted]	Not Interested
Germany				Not Interested
Germany				Missing
Germany				PI Retired
Germany				Not Interested
Germany				Missing
Italy				Missing
Italy				Missing
Italy				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]		[redacted]	Missing
Germany				Not Interested
Italy				Missing
Germany				Missing
Germany				Not Interested
Italy				Missing
Italy				Not Interested
Germany				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]		[redacted]	Not Interested
Italy				Missing
Germany				Missing
Germany				No Time/Not Taking Studies
Germany				Lack of Subject Population
Germany				Not Interested
Germany				Missing
Germany				Missing
Germany				Lack of Staff/Resources

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]	[redacted]	[redacted]	Missing
Italy				Missing
Germany				Lack of Staff/Resources
Germany				Missing
Germany				Missing
Italy				Missing
Germany				Missing
Italy				No Time/Not Taking Studies

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]		[redacted]	Not Interested
Germany				Not Interested
Italy				Lack of Staff/Resources
Italy				Missing
Italy				PI Retired
Germany				Missing
Germany				Missing
Italy				Missing
Italy				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]	[redacted]	[redacted]	Missing
Italy				Missing
Italy				Missing
Italy				Missing
Italy				Missing
Germany				PI Retired
Germany				Not Interested
Germany				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Germany	[redacted]		[redacted]	No Longer Doing Research
Germany				Not Interested
Germany				Missing
Germany				Missing
Germany				Missing
Germany				Not Interested
Germany				Lack of Subject Population
Germany				Not Interested
Germany				Missing

Country	Region	Site ID	Physician primary specialty	Reason for not participating
Italy	[redacted]	[redacted]	[redacted]	Lack of Subject Population
Italy				Lack of Staff/Resources
Germany				Missing
Germany				Lack of Subject Population
Italy				No Time/Not Taking Studies

Listing 3 Patient comorbidities

				Dysglycaemia			Hypertension		
Country	Site ID	Patient ID	Cohort	Comorbidity present	Diagnostic date	Ongoing/Stop date	Comorbidity present	Diagnostic date	Ongoing/Stop date
[redacted]									

							Dysglycaemia		Hypertension	
Country	Site ID	Patient ID	Cohort	Comorbidity present	Diagnostic date	Ongoing/Stop date	Comorbidity present	Diagnostic date		Ongoing/Stop date
[redacted]										

				Dysglycaemia				Hypertension	
Country	Site ID	Patient ID	Cohort	Comorbidity present	Diagnostic date	Ongoing/Stop date	Comorbidity present	Diagnostic date	Ongoing/Stop date
[redacted]									

							Dysglycaemia		Hypertension	
Country	Site ID	Patient ID	Cohort	Comorbidity present	Diagnostic date	Ongoing/Stop date	Comorbidity present	Diagnostic date	Ongoing/Stop date
[redacted]									

							Dysglycaemia		Hypertension	
Country	Site ID	Patient ID	Cohort	Comorbidity present	Diagnostic date	Ongoing/Stop date	Comorbidity present	Diagnostic date	Ongoing/Stop date
[redacted]									

							Dysglycaemia		Hypertension	
Country	Site ID	Patient ID	Cohort	Comorbidity present	Diagnostic date	Ongoing/Stop date	Comorbidity present	Diagnostic date		Ongoing/Stop date
[redacted]										

Listing 4 Body measurements

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Country	Site ID	Patient ID	Cohort	Non-adherent to escalation to 3.0mg dose at 12W	Weight (kg)	Height (cm)	BMI (Kg/m^2)	Measurement date	Time-point	Absolute weight change to Week 0	Relative weight change to Week 0	At least 5% Weight Loss?
[redacted]												

Listing 5 Study Treatment at Initiation and Study Completion

			At treatment initiation						At study completion	
Country	Patient ID	Brand name	Indication prescribed	Indication missing	Initial dose prescribed	Initial date of prescription	Is the study medication continuing?	If no, please provide reason	Last dose(mg) at study completion	Date of last dose of study medication
[redacted]										

			At treatment initiation						At study completion	
Country	Patient ID	Brand name	Indication prescribed	Indication missing	Initial dose prescribed	Initial date of prescription	Is the study medication continuing?	If no, please provide reason	Last dose(mg) at study completion	Date of last dose of study medication
[redacted]										

			At treatment initiation						At study completion	
Country	Patient ID	Brand name	Indication prescribed	Indication missing	Initial dose prescribed	Initial date of prescription	Is the study medication continuing?	If no, please provide reason	Last dose(mg) at study completion	Date of last dose of study medication
[redacted]										

			At treatment initiation						At study completion	
Country	Patient ID	Brand name	Indication prescribed	Indication missing	Initial dose prescribed	Initial date of prescription	Is the study medication continuing?	If no, please provide reason	Last dose(mg) at study completion	Date of last dose of study medication
[redacted]										

			At treatment initiation						At study completion	
Country	Patient ID	Brand name	Indication prescribed	Indication missing	Initial dose prescribed	Initial date of prescription	Is the study medication continuing?	If no, please provide reason	Last dose(mg) at study completion	Date of last dose of study medication
[redacted]										

			At treatment initiation						At study completion	
Country	Patient ID	Brand name	Indication prescribed	Indication missing	Initial dose prescribed	Initial date of prescription	Is the study medication continuing?	If no, please provide reason	Last dose(mg) at study completion	Date of last dose of study medication
[redacted]										

			At treatment initiation						At study completion	
Country	Patient ID	Brand name	Indication prescribed	Indication missing	Initial dose prescribed	Initial date of prescription	Is the study medication continuing?	If no, please provide reason	Last dose(mg) at study completion	Date of last dose of study medication
[redacted]										

			At treatment initiation						At study completion	
Country	Patient ID	Brand name	Indication prescribed	Indication missing	Initial dose prescribed	Initial date of prescription	Is the study medication continuing?	If no, please provide reason	Last dose(mg) at study completion	Date of last dose of study medication
[redacted]										

			At treatment initiation						At study completion	
Country	Patient ID	Brand name	Indication prescribed	Indication missing	Initial dose prescribed	Initial date of prescription	Is the study medication continuing?	If no, please provide reason	Last dose(mg) at study completion	Date of last dose of study medication
[redacted]										

			At treatment initiation						At study completion	
Country	Patient ID	Brand name	Indication prescribed	Indication missing	Initial dose prescribed	Initial date of prescription	Is the study medication continuing?	If no, please provide reason	Last dose(mg) at study completion	Date of last dose of study medication
[redacted]										

			At treatment initiation						At study completion	
Country	Patient ID	Brand name	Indication prescribed	Indication missing	Initial dose prescribed	Initial date of prescription	Is the study medication continuing?	If no, please provide reason	Last dose(mg) at study completion	Date of last dose of study medication
[redacted]										

			At treatment initiation						At study completion	
Country	Patient ID	Brand name	Indication prescribed	Indication missing	Initial dose prescribed	Initial date of prescription	Is the study medication continuing?	If no, please provide reason	Last dose(mg) at study completion	Date of last dose of study medication
[redacted]										

			At treatment initiation						At study completion	
Country	Patient ID	Brand name	Indication prescribed	Indication missing	Initial dose prescribed	Initial date of prescription	Is the study medication continuing?	If no, please provide reason	Last dose(mg) at study completion	Date of last dose of study medication
[redacted]										

			At treatment initiation						At study completion	
Country	Patient ID	Brand name	Indication prescribed	Indication missing	Initial dose prescribed	Initial date of prescription	Is the study medication continuing?	If no, please provide reason	Last dose(mg) at study completion	Date of last dose of study medication
[redacted]										

			At treatment initiation						At study completion	
Country	Patient ID	Brand name	Indication prescribed	Indication missing	Initial dose prescribed	Initial date of prescription	Is the study medication continuing?	If no, please provide reason	Last dose(mg) at study completion	Date of last dose of study medication
[redacted]										

			At treatment initiation						At study completion	
Country	Patient ID	Brand name	Indication prescribed	Indication missing	Initial dose prescribed	Initial date of prescription	Is the study medication continuing?	If no, please provide reason	Last dose(mg) at study completion	Date of last dose of study medication
[redacted]										

			At treatment initiation						At study completion	
Country	Patient ID	Brand name	Indication prescribed	Indication missing	Initial dose prescribed	Initial date of prescription	Is the study medication continuing?	If no, please provide reason	Last dose(mg) at study completion	Date of last dose of study medication
[redacted]										

Listing 6 Study Treatment log

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Country	Patient ID	Brand name	Prescription date	Dose(mg)	Dose (categorization)	Week after first prescription
[redacted]						

Note: This listing includes:

- repeated prescriptions dates
- changes dates and new associated doses
- last dose of medication

Note: Subject ID=[redacted] switched to a [redacted] mg Saxenda dose from [redacted] mg Victoza dose on [redacted]. However, since the patient started Victoza during the Index period, it was considered in the Victoza Analysis Set and therefore Dose(mg) is not displayed in the listing.

Listing 7 Switch from Victoza to Saxenda

Country	Patient ID	First prescription date	Dose (mg)	Switch from Victoza?	Date of last Victoza dose	Last Victoza dose
[redacted]						

Note: This listing includes:

- repeated prescriptions dates
- changes dates and new associated doses
- last dose of medication

Note: Subject ID=[redacted] switched to a [redacted] mg Saxenda dose from [redacted] mg Victoza dose on [redacted]. However, since the patient started Victoza during the Index period, it was considered in the Victoza Analysis Set and therefore Dose(mg) is not displayed in the listing.

15 References

1. Novo Nordisk. Saxenda® (Summary of Product Characteristics). Denmark, 2019
2. Novo Nordisk. Victoza® (Summary of Product Characteristics). Denmark, December 2018
3. Mangione-Smith R, Elliott MN, McDonald L, McGlynn EA. An observational study of antibiotic prescribing behavior and the Hawthorne effect. Health Serv Res 2002;37(6):1603-23.
4. World Medical Association (WMA) Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects. 64th WMA General Assembly, Brazil, October 2013.
5. Göddecke-Stellmann, J., R. Kawka, H. Lutter, T. Pütz, V. Schmidt-Seiwert, K. P. Schön, and M. Spangenberg. eds. 2011. "Metropolitan Areas in Europe." BBSR-Online-Publikation, Nr. 01/2011, Federal Institute for Research on Building, Urban Affairs and Spatial Development. Accessed 2 September 2019. http://www.espon-usespon.eu/dane/web_usespon_library_files/1200/de_metroareaeu_2011.pdf.