Real-world Use of Oral Semaglutide in Adults with Type 2 Diabetes: the PIONEER REAL Switzerland Multicentre, Prospective, Observational Study

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List of study sites and related IE

Site number	Site	IEC
1044	Gruppenpraxis Weststadt	Ethikkommission der Nordwest- und Zentralschweiz
1045	Kantonsspital Olten	Ethikkommission der Nordwest- und Zentralschweiz
1050	Universitaetsspital Basel	Ethikkommission der Nordwest- und Zentralschweiz
1051	HFR Fribourg - Kantonsspital Freiburg	Commission cantonale (VD) d'éthique de la recherche sur l'être humain
1052	friendlyDocs AG	Ethikkommission Ostschweiz
1053	Dr. Thurneysen Thomas Private practice	Commission cantonale (VD) d'éthique de la recherche sur l'être humain
1054	Diabetologie & Endokrinologie Baden	Ethikkommission der Nordwest- und Zentralschweiz
1055	Clinique de la Lignière	Commission cantonale (VD) d'éthique de la recherche sur l'être humain
1058	SCA: Primary Care Cardiological Practice	Comitato etico cantonale Ticino
1060	Gemeinschaftspraxis	Ethikkommission Ostschweiz (EKOS)
1061	Clinique de Genolier	Commission cantonale (VD) d'éthique de la recherche sur l'être humain
1062	Dr. Michaël Hagmann Private Practice	Commission cantonale (VD) d'éthique de la recherche sur l'être humain
1063	Elfenaupraxis	Kantonale Ethikkommission Bern (KEK-Bern)
1064	Generale-Beauliu Clinique	Commission cantonale (VD) d'éthique de la recherche sur l'être humain
1065	Dr. Mehran Faeli Private Praxis	Comitato etico cantonale Ticino
1048	MedicoPlus Health Care AG	Ethikkommission der Nordwest- und Zentralschweiz (EKNZ)
1049	Praxis Schöngrund	Ethikkommission der Nordwest- und Zentralschweiz (EKNZ)
1042	Luzerner Kantonsspital	Ethikkommission der Nordwest- und Zentralschweiz (EKNZ)
1043	Kantonsspital St. Gallen	Ethikkommission Ostschweiz (EKOS)
1067	Gruppenpraxis Weststadt	Ethikkommission der Nordwest- und Zentralschweiz (EKNZ)
1041	Dr. Beatrice Wirtner Muamba private practice	Etikkommission Zurich
1046	Kantonsspital Schaffhausen	Etikkommission Zurich

IEC, Independent Ethics Committee.

Table S1 Inclusion and exclusion criteria

Inclusion criteria For an eligible patient, all inclusion criteria must be answered “yes”. 1. Signed consent obtained before any study-related activities (study-related activities are any procedure related to the recording of data according to the protocol) 2. Diagnosed with type 2 diabetes mellitus 3. The decision to initiate treatment with commercially available oral semaglutide has been made by the patient/legally acceptable representative and the treating physician based on local label before and independently from the decision to include the patient in this study 4. Male or female, aged ≥18 years at the time of signing the informed consent 5. Available HbA_{1c} value ≤90 days prior to the ‘informed consent and treatment initiation visit’ (V1) or HbA_{1c} measurement taken in relation with the ‘informed consent and treatment initiation visit’ (V1) if in line with local clinical practice 6. Treatment naïve to injectable glucose-lowering drug(s). An exception is short-term insulin treatment for acute illness for a total of ≤14 days
Exclusion criteria For an eligible patient, all exclusion criteria must be answered “no”. 1. Previous participation in this study. Participation is defined as having given informed consent in this study 2. Treatment with any investigational drug within 30 days prior to enrolment into the study 3. Mental incapacity, unwillingness or language barriers precluding adequate understanding or cooperation

HbA_{1c} glycated haemoglobin

Table S2 HbA_{1c} (%) change from baseline to EOS, by baseline HbA_{1c} (in study – full analysis set)

HbA_{1c} (%)	
HbA_{1c}, ≤7%	
N	66
n	60
Observed mean at baseline	6.39
Estimated mean at EOS	6.08
Estimated mean change from baseline	−0.31
SE	0.14
95% CI	–0.59, –0.03
P value	0.0302
HbA_{1c}, >7 - ≤8%	
N	56
n	55
Observed mean at baseline	7.51
Estimated mean at EOS	6.69
Estimated mean change from baseline	–0.82
SE	0.14
95% CI	–1.09, –0.55
P value	<0.0001
HbA_{1c}, >8 - ≤9%	
N	31
n	26
Observed mean at baseline	8.47
Estimated mean at EOS	7.47
Estimated mean change from baseline	–1.00
SE	0.18
95% CI	–1.35, –0.65
P value	<0.0001
HbA_{1c}, >9%	
N	32

n	30
Observed mean at baseline	10.36
Estimated mean at EOS	8.26
Estimated mean change from baseline	–2.10
SE	0.17
95% CI	–2.44, –1.76
P value	<0.0001

CI, confidence interval, EOS, end of study; N, number of participants in full analysis set, n, number of participants in statistical analysis; SE, standard error.

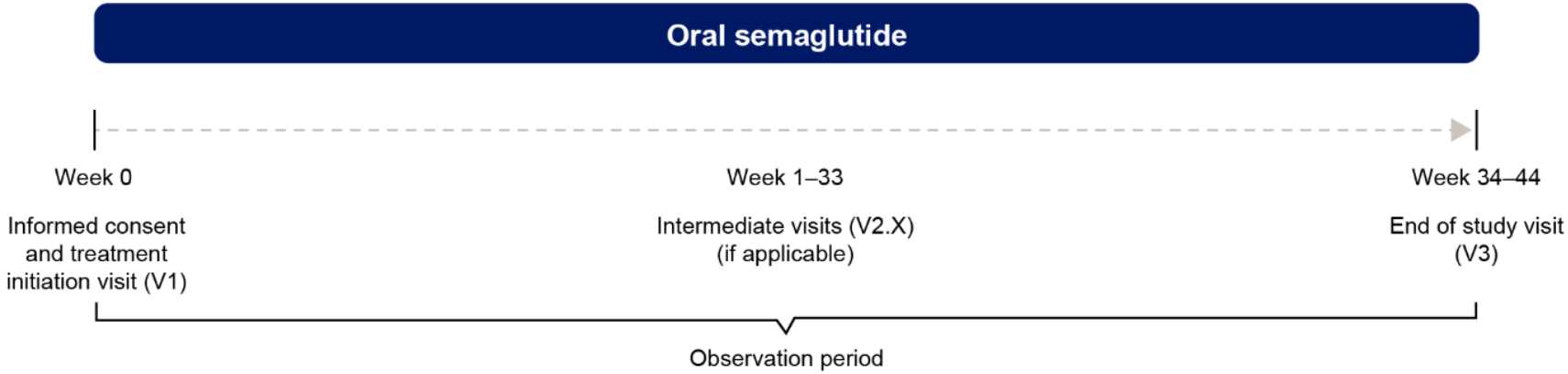
Table S3 HbA_{1c} (mmol/mol) change from baseline to EOS, by baseline HbA_{1c} (in study – full analysis set)

HbA_{1c} (mmol/mol)	
HbA_{1c}, ≤7%	
N	66
n	60
Observed mean at baseline	46.31
Estimated mean at EOS	42.95
Estimated mean change from baseline	−3.36
SE	1.54
95% CI	–6.41, –0.32
P value	0.0308
HbA_{1c}, >7 - ≤8%	
N	56
n	55
Observed mean at baseline	58.61
Estimated mean at EOS	49.61
Estimated mean change from baseline	–9.00
SE	1.48
95% CI	–11.93, –6.07
P value	<0.0001
HbA_{1c}, >8 - ≤9%	
N	31
n	26
Observed mean at baseline	69.03
Estimated mean at EOS	58.15
Estimated mean change from baseline	–10.88
SE	1.94
95% CI	–14.71, –7.04
P value	<0.0001
HbA_{1c}, >9%	
N	32

n	30
Observed mean at baseline	89.70
Estimated mean at EOS	66.77
Estimated mean change from baseline	–22.93
SE	1.87
95% CI	–26.62, –19.24
P value	<0.0001

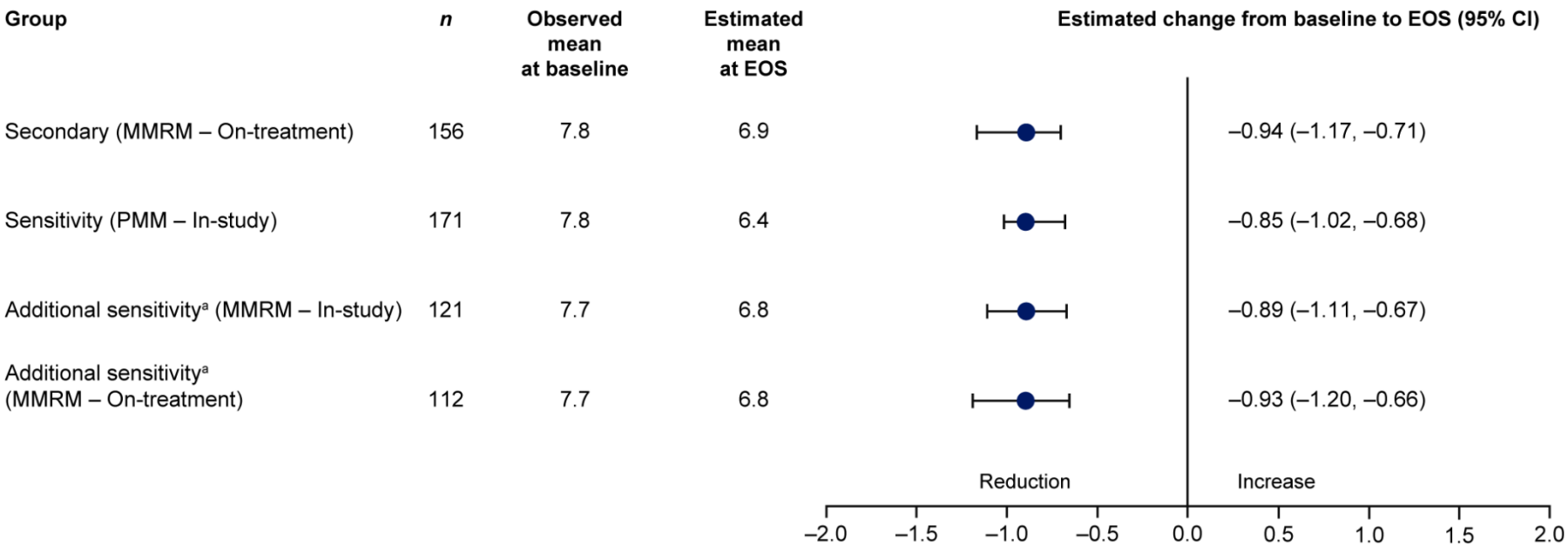
CI, confidence interval, EOS, end of study; N, number of participants in full analysis set, n, number of participants in statistical analysis; SE, standard error.

Fig. S1 Study design



V visit

Fig. S2 Secondary and sensitivity analysis of the primary endpoint (change from baseline in HbA_{1c} [%-points])



CI confidence interval, *EOS* end of study, *HbA_{1c}* glycated haemoglobin, *MMRM* mixed model for repeated measurements, *PMM* pattern mixture model

n is the total number of patients contributing to the statistical analysis

Estimates (95% CI) from the adjusted models are plotted

[a]Where participants with an EOS visit outside the EOS window were excluded from the analyses