Supplemental Materials

Title: Patient-Reported Outcomes in People with Type 2 Diabetes Receiving Tirzepatide in the SURPASS Clinical Trial Programme

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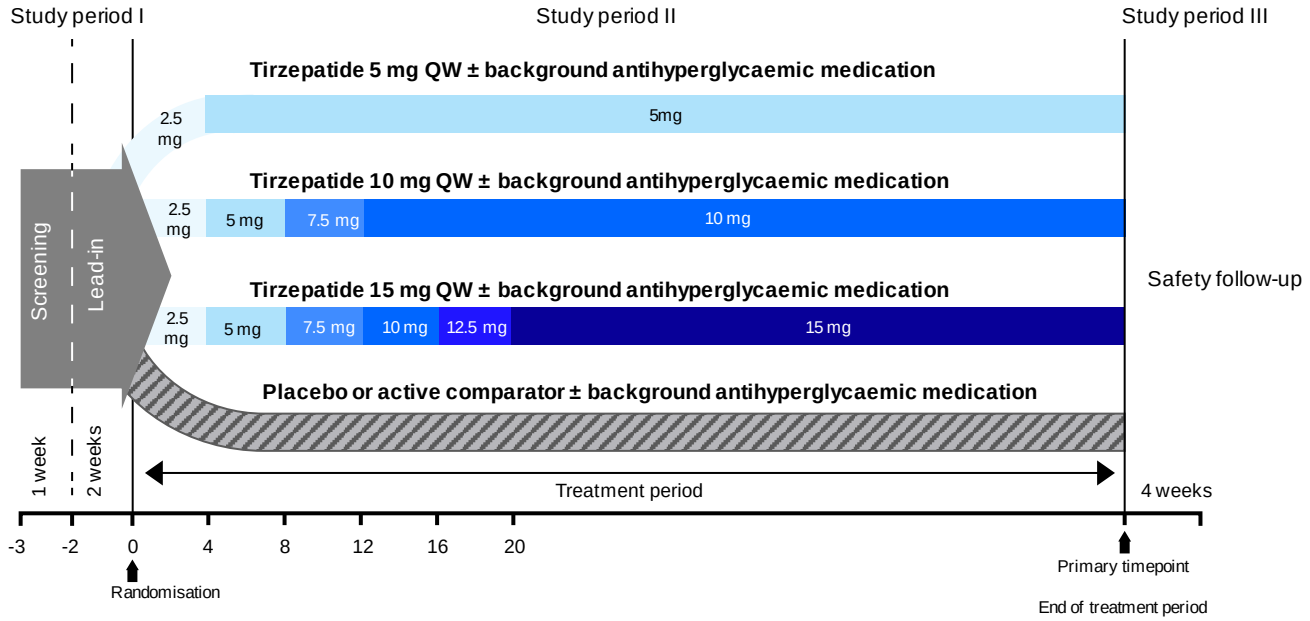

Study (design)	Sample size, randomisation ratio, background glucose-lowering therapy	Comparator	Primary timepoint
SURPASS-1 (randomised, double-blind, placebo-controlled, parallel, multicentre)	N=478 1:1:1:1 None	Placebo QW	Week 40
SURPASS-2 (randomised, open-label, active-controlled, parallel, multicentre)	N=1878 1:1:1:1 Metformin	Semaglutide 1 mg QW	Week 40
SURPASS-3 (randomised, open-label, active-controlled, parallel, multicentre)	N=1437 1:1:1:1 Metformin ± SGLT-2i	Titrated insulin degludec QD	Week 52
SURPASS-4 (randomised, open-label, active-controlled, parallel, multicentre)	N=1995 1:1:1:3 1–3 oral antihyperglycaemic medications (metformin, SGLT-2i and/or SU)	Titrated insulin glargine QD	Week 52
SURPASS-5 (randomised, double-blind, placebo-controlled, parallel, multicentre)	N=475 1:1:1:1 Titrated insulin glargine ± metformin	Placebo QW	Week 40

Fig. S1 Overview of the study designs of the SURPASS-1 to -5 clinical trials. Abbreviations: N=number of randomised participants who took at least 1 dose of study drug (modified intent-to-treat); QD=once daily; QW=once weekly; SGLT-2i=sodium-glucose cotransporter-2 inhibitor; SU=sulfonylurea.

Table S1 Baseline demographics and clinical characteristics of patients in SURPASS-1 to -5 clinical trials

Studies	**SURPASS-1** **N=478**	**SURPASS-2** **N=1878**	**SURPASS-3** **N=1437**	**SURPASS-4** **N=1995**	**SURPASS-5** **N=475**
Age (years)	54.1 ± 11.9	56.6 ± 10.4	57.4 ± 10.0	63.6 ± 8.6	60.6 ± 9.9
Female, n (%)	231 (48.3)	996 (53.0)	635 (44.2)	749 (37.5)	211 (44.4)
Race, n (%)					
White	170 (35.6)	1551 (82.6)	1307 (91.0)	1629 (81.8)	380 (80.0)
Asian	168 (35.1)	25 (1.3)	76 (5.3)	70 (3.5)	85 (17.9)
HbA1c (%)	**7.94 ± 0.87**	**8.28 ± 1.03**	**8.17 ± 0.91**	**8.52 ± 0.88**	**8.31 ± 0.85**
Fasting serum glucose (mg/dL)	153.6 ± 39.8	172.9 ± 51.5	169.3 ± 45.9	171.2 ± 50.8	162.4 ± 51.3
Duration of T2D (years)	4.7 ± 5.4	8.6 ± 6.5	8.4 ± 6.2	11.8 ± 7.5	13.3 ± 7.3
BMI (kg/m^2)	31.9 ± 6.6	34.2 ± 6.9	33.5 ± 6.1	32.6 ± 5.5	33.4 ± 6.1
Weight (kg)	85.9 ± 19.8	93.7 ± 21.9	94.3 ± 20.1	90.3 ± 18.7	95.2 ± 21.6

Data are mean ± SD unless otherwise indicated; modified intent-to-treat population.

BMI=body mass index; HbA1c=glycated haemoglobin; SD=standard deviation; T2D=type 2 diabetes.

Table S2 Summary of any AE leading to treatment discontinuation and gastrointestinal adverse events of interest (any severity) in SURPASS-1 to -5 clinical trials

	N	Any AE leading to treatment discontinuation*	Gastrointestinal AEs of interest (any severity)		
			Nausea	Diarrhoea	Vomiting
SURPASS-1 (monotherapy) (primary endpoint at Week 40)					
Tirzepatide 5 mg	121	4 (3%)	14 (12%)	14 (12%)	4 (3%)
Tirzepatide 10 mg	121	6 (5%)	16 (13%)	17 (14%)	3 (2%)
Tirzepatide 15 mg	121	8 (7%)	22 (18%)	14 (12%)	7 (6%)
Placebo	115	3 (3%)	7 (6%)	9 (8%)	2 (2%)
SURPASS-2 (add-on to metformin) (primary endpoint at Week 40)					
Tirzepatide 5 mg	470	28 (6%)	82 (17%)	62 (13%)	27 (6%)
Tirzepatide 10 mg	469	40 (9%)	90 (19%)	77 (16%)	40 (9%)
Tirzepatide 15 mg	470	40 (9%)	104 (22%)	65 (14%)	46 (10%)
Semaglutide 1 mg	469	19 (4%)	84 (18%)	54 (12%)	39 (8%)
SURPASS-3 (add-on to metformin ± SGLT-2i) (primary endpoint at Week 52)					
Tirzepatide 5 mg	358	25 (7%)	41 (12%)	55 (15%)	21 (6%)
Tirzepatide 10 mg	360	37 (10%)	81 (23%)	60 (17%)	34 (9%)
Tirzepatide 15 mg	359	39 (11%)	85 (24%)	56 (16%)	36 (10%)
Insulin degludec	360	5 (1%)	6 (2%)	14 (4%)	4 (1%)
SURPASS-4 (add-on to ± metformin ± sulfonylurea ± SGLT-2i) (primary endpoint at Week 52)					
Tirzepatide 5 mg	329	37 (11%)	39 (12%)	41 (13%)	16 (5%)
Tirzepatide 10 mg	328	28 (9%)	53 (16%)	65 (20%)	27 (8%)
Tirzepatide 15 mg	338	36 (11%)	76 (23%)	74 (22%)	29 (9%)
Insulin glargine	1000	54 (5%)	23 (2%)	44 (4%)	16 (2%)
SURPASS-5 (add-on to insulin glargine ± metformin) (primary endpoint at Week 40)					
Tirzepatide 5 mg	116	7 (6%)	15 (13%)	14 (12%)	8 (7%)
Tirzepatide 10 mg	119	10 (8%)	21 (18%)	15 (13%)	9 (8%)
Tirzepatide 15 mg	120	13 (11%)	22 (18%)	25 (21%)	15 (13%)
Placebo	120	3 (3%)	3 (3%)	12 (10%)	3 (3%)

Data are n (%) in the safety population (modified intent-to-treat population, using all data from the start of treatment to the end of the safety follow-up period). Participants might be counted in more than one category. *Consistent with the low rate of study treatment discontinuation, ≤3% of patients who received at least one dose of tirzepatide in SURPASS-1 to -5 discontinued treatment because of nausea, vomiting or diarrhoea [9]. AE=adverse event; SGLT-2i=sodium-glucose co-transporter-2 inhibitor.

Table S3 Patient-reported outcomes from the SURPASS-1 to -5 clinical trials

SURPASS-1				
mITT[a], Week 40	**Tirzepatide 5 mg N=121**	**Tirzepatide 10 mg N=121**	**Tirzepatide 15 mg N=120**	**Placebo N=113**
IW-SP	**n=108[b]**	**n=104**	**n=94**	**n=71**
Transformed score[c]	65.7	67.6	68.2	67.5
Change from baseline[d]	10.5[*]	14.5[*]	13.8[*]	5.9[*]
Difference vs placebo[d]	**4.7** (-0.9, 10.2)	**8.6**[†] (3.0, 14.2)	**7.9**[†] (2.2, 13.7)	N/A
APPADL	**n=108**	**n=104**	**n=94**	**n=71**
Transformed score[c]	70.7	79.4	79.7	77.1
Change from baseline[d]	4.5[*]	4.8[*]	5.9[*]	1.8
Difference vs placebo[d]	**2.7** (-1.4, 6.8)	**3.0** (-1.1, 7.1)	**4.0** (-0.2, 8.2)	N/A
EQ-5D-5L index score	**n=108**	**n=104**	**n=93**	**n=70**
Score[c]	0.84	0.88	0.88	0.87
Change from baseline[d]	0.03[*]	0.03[*]	0.04[*]	0.00
Difference vs placebo[d]	**0.03** (-0.01, 0.07)	**0.03** (-0.01, 0.07)	**0.04** (0.00, 0.08)	N/A
EQ VAS	**n=108**	**n=104**	**n=93**	**n=70**
Score[c]	80.4	82.8	83.8	83.4
Change from baseline[d]	4.2[*]	5.3[*]	6.4[*]	0.2
Difference vs placebo[d]	**4.0**[†] (0.8, 7.2)	**5.1**[†] (2.0, 8.3)	**6.2**[†] (3.0, 9.5)	N/A
SURPASS-2				
mITT[a], Week 40	**Tirzepatide 5 mg N=470**	**Tirzepatide 10 mg N=469**	**Tirzepatide 15 mg N=469**	**Semaglutide 1 mg N=468**
IW-SP	**n=422[b]**	**n=405**	**n=400**	**n=416**
Transformed score[c]	69.7	69.0	66.9	70.4
Change from baseline[d]	11.5[*]	11.2[*]	12.6[*]	8.7[*]
Difference vs semaglutide[d]	**2.8** (0.0, 5.7)	**2.6** (-0.3, 5.4)	**3.9**[†] (1.1, 6.8)	N/A
APPADL	**n=422**	**n=403**	**n=400**	**n=416**
Transformed score[c]	69.8	69.2	68.8	68.5
Change from baseline[d]	5.7[*]	6.6[*]	7.9[*]	5.4[*]
Difference vs semaglutide[d]	**0.3** (-1.9, 2.4)	**1.2** (-1.0, 3.4)	**2.6**† (0.4, 4.7)	N/A
IWQOL-Lite-CT	**n=417**	**n=401**	**n=394-395**	**n=414**
Physical score[c]	65.8	64.3	62.8	66.8
Change from baseline[d]	9.4[*]	9.9[*]	11.3[*]	7.3[*]
Difference vs semaglutide[d]	**2.1** (-0.1, 4.4)	**2.6**[†] (0.4, 4.9)	**4.0**[†] (1.8, 6.3)	N/A
Physical function score[c]	65.5	63.9	62.4	67.0
Change from baseline[d]	10.4[*]	10.6[*]	12.2[*]	7.9[*]
Difference vs semaglutide[d]	**2.6**[†] (0.2, 5.0)	**2.8**[†] (0.4, 5.2)	**4.4**[†] (1.9, 6.8)	N/A
Psychosocial score[c]	72.0	71.8	69.5	74.1
Change from baseline[d]	9.0[*]	9.2[*]	10.2[*]	7.6[*]
Difference vs semaglutide[d]	**1.5** (-0.5, 3.5)	**1.6** (-0.4, 3.7)	**2.7**† (0.6, 4.7)	N/A
Total score[c]	69.8	69.2	67.3	71.5
Change from baseline[d]	9.2[*]	9.4[*]	10.6[*]	7.4[*]
Difference vs semaglutide[d]	**1.7** (-0.2, 3.6)	**2.0**[†] (0.0, 3.9)	**3.1**[†] (1.2, 5.1)	N/A
DTSQ	**n=419**	**n=399**	**n=398**	**n=411**
DTSQs baseline[c]	27.2	27.8	27.9	27.6

DTSQc Week 40[d]	15.7	15.6	16.1	15.8
Difference vs semaglutide[d]	**-0.1** (-0.6, 0.4)	**-0.3** (-0.8, 0.3)	**0.3** (-0.3, 0.8)	N/A
Hyperglycaemia	**n=418**	**n=399**	**n=398**	**n=411**
DTSQs baseline[c]	3.9	3.9	3.8	3.6
DTSQc Week 40[d]	-1.3	-1.4	-1.5	-1.1
Difference vs semaglutide[d]	**-0.2** (-0.5, 0.0)	**-0.3** (-0.5, 0.0)	**-0.4**[†] (-0.7, -0.1)	N/A
Hypoglycaemia	**n=416**	**n=398**	**n=398**	**n=412**
DTSQs baseline[c]	1.2	1.1	1.2	1.1
DTSQc Week 40[d]	-0.7	-0.7	-0.8	-0.7
Difference vs semaglutide[d]	**-0.1** (-0.3, 0.2)	**-0.0** (-0.3, 0.3)	**-0.1** (-0.4, 0.2)	N/A
EQ-5D-5L index score	**n=415**	**n=401**	**n=395**	**n=413**
Score	0.82	0.82	0.82	0.82
Change from baseline[d]	0.04[*]	0.04[*]	0.04[*]	0.04[*]
Difference vs semaglutide[d]	**0.00** (-0.02, 0.02)	**0.01** (-0.01, 0.03)	**0.00** (-0.02, 0.02)	N/A
EQ VAS	**n=418**	**n=402**	**n=395**	**n=414**
Score	74.3	75.3	75.8	74.6
Change from baseline[d]	8.3[*]	8.8[*]	8.7[*]	7.8[*]
Difference vs semaglutide[d]	**0.5** (-1.2, 2.2)	**1.1** (-0.7, 2.8)	**1.0** (-0.8, 2.7)	N/A
SURPASS-3				
mITT[a], Week 52	**Tirzepatide 5 mg N=358**	**Tirzepatide 10 mg N=360**	**Tirzepatide 15 mg N=358**	**Insulin degludec N=359**
EQ-5D-5L index score	**n=309[b]**	**n=295**	**n=294**	**n=318**
Score	0.85	0.83	0.85	0.83
Change from baseline[d]	0.02[*]	0.03[*]	0.03[*]	0.01
Difference vs insulin degludec[d]	**0.01** (-0.01, 0.03)	**0.02** (0.00, 0.04)	**0.02** (0.00, 0.04)	N/A
EQ VAS	**n=310**	**n=296**	**n=295**	**n=318**
Score[c]	76.9	77.3	78.1	76.7
Change from baseline[d]	6.0[*]	6.6[*]	6.4[*]	2.3[*]
Difference vs insulin degludec[d]	**3.7**[†] (1.8, 5.5)	**4.3**[†] (2.4, 6.2)	**4.1**[†] (2.2, 6.0)	N/A
IW-SP	**n=312**	**n=297**	**n=297**	**n=321**
Transformed score[c]	67.9	68.9	67.8	69.5
Change from baseline[d]	7.3[*]	11.8[*]	10.3[*]	-1.4
Difference vs insulin degludec[d]	**8.7**[†] (5.3, 12.1)	**13.2**[†] (9.8, 16.7)	**11.7**[†] (8.2, 15.1)	N/A
APPADL	**n=312**	**n=297**	**n=297**	**n=320**
Transformed score[c]	71.3	69.8	71.1	70.5
Change from baseline[d]	3.0[*]	5.5[*]	6.3[*]	-1.0
Difference vs insulin degludec[d]	**4.0**[†] (1.6, 6.4)	**6.5**[†] (4.1, 8.9)	**7.3**[†] (4.9, 9.7)	N/A
DTSQ	**n=305**	**n=293**	**n=292**	**n=313**
DTSQs baseline[c]	27.7	28.1	28.0	27.8
DTSQc Week 52[d]	15.6	15.5	15.6	12.6
Difference vs insulin degludec[d]	**3.0**[†] (2.3, 3.8)	**2.9**[†] (2.2, 3.7)	**3.0**[†] (2.2, 3.7)	N/A

Hyperglycaemia[c]	**n=306**	**n=293**	**n=292**	**n=312**
DTSQs baseline[c]	3.6	3.5	3.5	3.3
DTSQc Week 52[d]	-1.4	-1.4	-1.6	-1.1
Difference vs insulin degludec[d]	**-0.3** (-0.6, 0.1)	**-0.3** (-0.6, 0.1)	**-0.5**[†] (-0.8, -0.2)	N/A
Hypoglycaemia[c]	**n=306**	**n=293**	**n=292**	**n=313**
DTSQs baseline[c]	0.9	0.8	0.9	0.9
DTSQc Week 52[d]	-1.1	-0.9	-1.0	-0.7
Difference vs insulin degludec[d]	**-0.4**[†] (-0.7, -0.1)	**-0.2** (-0.5, 0.2)	**-0.3** (-0.6, 0.1)	N/A
SURPASS-4				
mITT[a], Week 52	**Tirzepatide 5 mg N=328**	**Tirzepatide 10 mg N=326**	**Tirzepatide 15 mg N=337**	**Insulin glargine N=998**
EQ-5D-5L index score	**n=282 [b]**	**n=289**	**n=295**	**n=887**
Score[c]	0.80	0.76	0.77	0.79
Change from baseline[d]	0.04[*]	0.04[*]	0.04[*]	0.00
Difference vs insulin glargine[d]	**0.04**[†] (0.02, 0.07)	**0.04**[†] (0.01, 0.06)	**0.04**[†] (0.01, 0.06)	N/A
EQ VAS	**n=284**	**n=290**	**n=296**	**n=897**
Score[c]	75.4	73.8	74.5	75.3
Change from baseline[d]	8.1[*]	6.5[*]	6.3[*]	3.0[*]
Difference vs insulin glargine[d]	**5.1**[†] (3.3, 6.9)	**3.5**[†] (1.7, 5.3)	**3.3**[†] (1.6, 5.1)	N/A
IW-SP	**n=285**	**n=290**	**n=295**	**n=903**
Transformed score[c]	70.5	68.6	70.5	72.5
Change from baseline[d]	10.4[*]	12.5[*]	11.6[*]	2.9*
Difference vs insulin glargine[d]	**7.5**[†] (4.7, 10.3)	**9.7**[†] (6.9, 12.5)	**8.8**[†] (6.0, 11.5)	N/A
APPADL	**n=285**	**n=291**	**n=296**	**n=903**
Transformed score[c]	63.8	61.4	61.5	63.4
Change from baseline[d]	5.9[*]	5.6[*]	6.1[*]	-1.1
Difference vs insulin glargine[d]	**7.0**[†] (4.6, 9.4)	**6.7**[†] (4.3, 9.1)	**7.2**[†] (4.8, 9.5)	N/A
DTSQ	**n=278**	**n=286**	**n=290**	**n=884**
DTSQs baseline[c]	28.5	27.8	27.7	27.9
DTSQc Week 52[d]	15.3	15.7	15.3	13.7
Difference vs insulin glargine[d]	**1.6**[†] (1.0, 2.3)	**2.0**[†] (1.4, 2.6)	**1.6**[†] (1.0, 2.3)	N/A
Hyperglycaemia	**n=278**	**n=287**	**n=291**	**n=883**
DTSQs baseline[c]	3.4	3.6	3.7	3.4
DTSQc Week 52[d]	-0.9	-1.2	-1.5	-0.9
Difference vs insulin glargine[d]	**-0.0** (-0.3, 0.3)	**-0.3**[†] (-0.6, -0.0)	**-0.6**[†] (-0.9, -0.4)	N/A
Hypoglycaemia	**n=278**	**n=286**	**n=290**	**n=881**
DTSQs baseline[c]	0.9	1.1	1.0	1.0
DTSQc Week 52[d]	-0.9	-0.7	-0.8	-0.4
Difference vs insulin glargine[d]	**-0.5**[†] (-0.8, -0.2)	**-0.3**[†] (-0.6, -0.1)	**-0.4**[†] (-0.7, -0.1)	N/A
SURPASS-5				
mITT[a], Week 40	**Tirzepatide 5 mg N=116**	**Tirzepatide 10 mg N=118**	**Tirzepatide 15 mg N=118**	**Placebo N=119**

EQ-5D-5L index score	**n=105[b]**	**n=105**	**n=98**	**n=111**
Score[c]	0.78	0.80	0.82	0.82
Change from baseline[d]	-0.02	0.04*	0.03	-0.03
Difference vs placebo[d]	**0.01** (-0.03, 0.05)	**0.07**† (0.03, 0.11)	**0.06**† (0.02, 0.11)	N/A
EQ VAS	**n=105**	**n=106**	**n=98**	**n=111**
Score[c]	75.0	73.9	78.2	77.1
Change from baseline[d]	1.7	5.8*	2.3	-0.9
Difference vs placebo[d]	**2.6** (-1.2, 6.3)	**6.7**† (3.0, 10.5)	**3.2** (-0.6, 7.0)	N/A
IW-SP	**n=106**	**n=106**	**n=98**	**n=111**
Transformed score[c]	62.9	63.4	64.8	64.7
Change from baseline[d]	5.2*	12.0*	14.0*	1.7
Difference vs placebo[d]	**3.5** (-1.5, 8.5)	**10.3**† (5.3, 15.3)	**12.3**† (7.2, 17.4)	N/A
APPADL	**n=106**	**n=106**	**n=98**	**n=111**
Transformed score[c]	63.6	68.0	69.1	69.1
Change from baseline[d]	1.6	5.0*	6.9*	-1.3
Difference vs placebo[d]	**3.0** (-1.0, 6.9)	**6.3**† (2.3, 10.3)	**8.3**† (4.2, 12.3)	N/A
DTSQ	**n=105**	**n=105**	**n=95**	**n=109**
DTSQs baseline[c]	29.1	29.5	29.0	29.2
DTSQc Week 40[d]	14.1	14.5	13.7	10.7
vs placebo[d]	**3.4**† (1.9, 4.8)	**3.7**† (2.3, 5.2)	**2.9**† (1.4, 4.4)	N/A
Hyperglycaemia	**n=105**	**n=105**	**n=95**	**n=109**
DTSQs baseline[c]	2.8	3.2	2.9	2.8
DTSQc Week 40[d]	-1.8	-1.4	-1.6	-0.9
Difference vs placebo[d]	**-1.0**† (-1.5, -0.5)	**-0.6**† (-1.0, -0.1)	**-0.7**† (-1.2, -0.2)	N/A
Hypoglycaemia	**n=105**	**n=105**	**n=95**	**n=108**
DTSQs baseline[c]	1.0	0.8	0.8	0.9
DTSQc Week 40[d]	-0.5	-0.1	-0.6	-0.4
Difference vs placebo[d]	**-0.0** (-0.6, 0.5)	**0.4** (-0.2, 0.9)	**-0.2** (-0.8, 0.3)	N/A

Data are LSM (baseline and change from baseline) and LSM (95% CI) treatment differences, unless otherwise noted.

[a]mITT-efficacy analyses set excludes patients who discontinued study drug due to inadvertent enrolment and data after rescue or study drug discontinuation.

[b]n=number of patients with baseline and postbaseline values.

[c]Baseline values.

[d]From analysis of covariance with last observation carried forward.

*p<0.05 versus baseline.

†p<0.05 versus comparator.

APPADL=Ability to Perform Physical Activities of Daily Living; CI=confidence interval; DTSQ=Diabetes Treatment Satisfaction Questionnaire; DTSQc=DTSQ change; DTSQs=DTSQ status; IWQOL-Lite-CT=Impact

of Weight on Quality of Life-Lite Clinical Trials Version; IW-SP=Impact of Weight on Self-Perceptions; LSM=least squares mean; mITT=modified intent-to-treat; n=number of patients with baseline and post-baseline values; N/A=not applicable; VAS=visual analogue scale.

Table S4 DTSQc total, hypoglycemia and hyperglycemia scores at primary timepoint (Week 40) and changes from baseline to primary timepoint (Week 40) in EQ-5D-5L index scores and EQ VAS from SURPASS-2, by gastrointestinal adverse event category (with or without NVD) for patients receiving tirzepatide-pooled (5, 10 or 15 mg), or semaglutide (1 mg)

mITT[a], Week 40	Tirzepatide-pooled (N=1408)		Semaglutide 1mg (N=468)	
	With NVD	No NVD	With NVD	No NVD
DTSQc:				
DTSQc total treatment satisfaction score				
n, Week 40	327	889	99	312
DTSQc, Week 40	15.4 (15.0, 15.8)	16.0 (15.7, 16.2)	15.9 (15.1, 16.7)	15.8 (15.4, 16.2)
Hypoglycaemia				
n, Week 40	325	887	99	313
DTSQc, Week 40[d]	-0.60 (-0.82, -0.38)	-0.78 (-0.92, -0.65)	-0.36 (-0.76, 0.03)	-0.76 (-0.99, -0.54)
Hyperglycaemia				
n, Week 40	327	888	99	312
DTSQc, Week 40	-1.45 (-1.66, -1.23)	-1.37 (-1.50, -1.24)	-1.15 (-1.54, -0.77)	-1.07 (-1.29, -0.85)
EQ-5D-5L index score				
n, baseline	410	991	122	345
Baseline index score	0.78	0.84	0.76	0.83
n, Week 40	332	879	99	314
Change from baseline in index score	0.01 (-0.00, 0.03)	0.05 (0.04, 0.06)	0.01 (-0.03, 0.04)	0.05 (0.03, 0.06)
EQ VAS				
n, baseline	409	996	123	345
Baseline VAS	73.5	75.7	70.7	76.1
n, Week 40	331	884	100	314
Change from baseline in VAS	7.7 (6.3, 9.1)	9.0 (8.1, 9.8)	7.9 (5.4, 10.5)	7.6 (6.2, 9.0)

[a]Modified intent-to-treat efficacy analyses set excludes patients who discontinued study drug due to inadvertent enrolment and data after rescue or study drug discontinuation. NVD is an adverse event of any severity. Baseline data are means. Change from baseline results were analysed using ANCOVA models for endpoint measures with LOCF imputation. Change = baseline score + treatment + gastrointestinal category (NVD yes, no) + treatment*gastrointestinal category (NVD yes, no). Week 40 data are LSM (95% CI).

ANCOVA=analysis of covariance; CI=confidence interval; DTSQc=Diabetes Treatment Satisfaction Questionnaire change; LSM=least squares mean; LOCF, last observation carried forward; mITT=modified intent-to-treat; NVD=nausea, vomiting or diarrhoea; VAS=visual analogue scale.