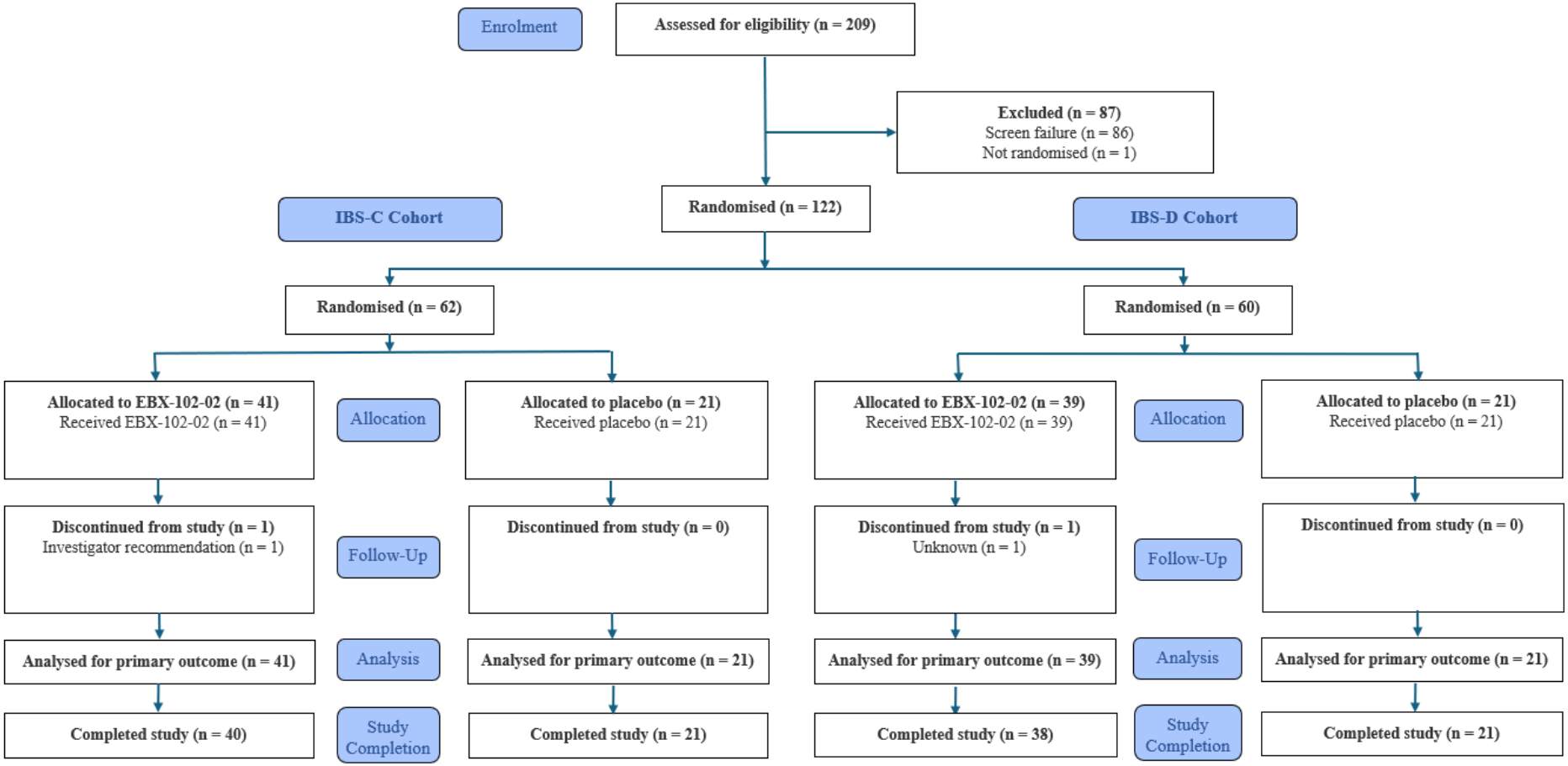
TrIuMPH: Treating IBS with an Intestinal Microbiota Product for Health

Participant Disposition

Figure 1: Participant Disposition Flow Diagram - IBS-C and IBS-D cohorts



Analysis set summary

Table 1: Analysis populations - IBS-C and IBS-D cohort

	Number of patients	Statistic	EBX-102-02		Placebo		Overall	
IBS-C	Included in screening population	N					116	
	Included in intent-to-treat (ITT)	n (%)	41	(100)	21	(100)	62	(100)
	Included in safety population	n (%)	41	(100)	21	(100)	62	(100)
	Included in per-protocol population	n (%)	40	(97.6)	19	(90.5)	59	(95.2)
IBS-D	Included in screening population	N					93	
	Included in intent-to-treat (ITT)	n (%)	39	(100)	21	(100)	60	(100)
	Included in safety population	n (%)	39	(100)	21	(100)	60	(100)
	Included in per-protocol population	n (%)	39	(100)	21	(100)	60	(100)

Baseline Characteristics

Table 2: Demographics and Baseline characteristics; IBS-C safety population

		Statistic	EBX-102-02		Placebo		Overall	
		N	41		21		62	
Age (years)		Mean (SD)	36.9	(11.3)	36.2	(9.9)	36.6	(10.8)
Sex	Female	n (%)	31	(75.6)	18	(35.7)	49	(79.0)
	Male	n (%)	10	(24.4)	3	(14.3)	13	(21.0)
Race	White	n (%)	30	(73.2)	18	(85.7)	48	(77.4)
	Asian	n (%)	5	(12.2)	2	(9.5)	7	(11.3)
	Black or African American	n (%)	2	(4.9)	0		2	(3.2)
	Other	n (%)	4	(9.8)	0		4	(6.5)
Height (cm)		Mean (SD)	167.0	(8.4)	166.6	(7.1)	167.5	(7.9)
Weight (kg)		Mean (SD)	66.4	(10.5)	64.9	(9.3)	65.9	(10.1)
BMI (kg/m^2)		Mean (SD)	23.5	(3.4)	23.5	(3.6)	23.5	(3.5)

Table 3: Demographics and Baseline characteristics; IBS-D safety population

		Statistic	EBX-102-02		Placebo		Overall	
		N	39		21		60	
Age (years)		Mean (SD)	36.5	(11.8)	30.5	(9.0)	34.4	(11.2)
Sex	Female	n (%)	24	(61.5)	15	(71.4)	39	(65.0)
	Male	n (%)	15	(38.5)	6	(28.6)	21	(35.0)
Race	White	n (%)	30	(76.9)	15	(71.4)	45	(75.0)
	Asian	n (%)	6	(15.4)	3	(14.3)	9	(15.0)
	Black or African American	n (%)	0		2	(9.5)	2	(3.3)
	Other	n (%)	2	(5.1)	1	(4.8)	3	(5.0)
	Multiple	n (%)	1	(2.6)	0		1	(1.7)
Height (cm)		Mean (SD)	169.2	(9.2)	168.7	(10.6)	169.0	(9.6)
Weight (kg)		Mean (SD)	76.1	(20.0)	69.8	(12.2)	73.9	(17.8)
BMI (kg/m^2)		Mean (SD)	26.5	(6.1)	24.5	(3.6)	25.8	(5.4)

Outcome Measures

Primary outcome: safety and tolerability – incidence and type of adverse event

Table 4: Overview of Treatment Emergent Adverse Events (TEAE) - IBS-C and IBS-D

Characteristic	Statistic	EBX-102-02		Placebo		Overall	
	N	80		42		122	
Any TEAE	n (%)	56	(70.0)	31	(73.8)	87	(71.3)
TEAE related to study treatment	n (%)	30	(37.5)	19	(45.2)	49	(40.2)
Serious TEAE	n (%)	1	(1.3)	0		1	(0.8)
Maximum severity							
Mild	n (%)	39	(48.8)	26	(61.9)	65	(53.3)
Moderate	n (%)	14	(17.5)	4	(9.5)	18	(14.8)
Severe	n (%)	3	(3.8)	1	(2.4)	4	(3.3)
TEAE leading to:							
Treatment discontinuation	n (%)	1	(1.3)	0		1	(0.8)
Study discontinuation	n (%)	1	(1.3)	0		1	(0.8)
Death	n (%)	0		0		0	

Table 5: Incidence of related TEAE by System Organ Class and Preferred Term in 2 or more patients- IBS-C and IBS-D cohorts

System Organ Class/ preferred term	EBX-102-02 N=80			Placebo N=42			Overall N=122		
	Number patients	%	Number of events	Number patients	%	Number of events	Number patients	%	Number of events
Number of patients with at least one related TEAE	30	37.5	118	19	45.2	40	49	40.2	158
Gastrointestinal disorders	28	35	92	19	45.2	34	47	38.5	126
Nausea	14	17.5	17	5	11.9	5	19	15.6	22
Abdominal distension	11	13.8	14	6	14.3	7	17	13.9	21
Diarrhoea	10	12.5	13	3	7.1	4	13	10.7	17
Abdominal pain	7	8.8	10	4	9.5	4	11	9	14
Flatulence	7	8.8	7	3	7.1	3	10	8.2	10
Abdominal pain upper	6	7.5	8	3	7.1	3	9	7.4	11
Vomiting	3	3.8	3	2	4.8	2	5	4.1	5
Eructation	2	2.5	2	1	2.4	1	3	2.5	3
Faeces discoloured	3	3.8	3	0	0	0	3	2.5	3
Gastroesophageal reflux disease	2	2.5	2	1	2.4	1	3	2.5	3
Constipation	1	1.3	1	1	2.4	1	2	1.6	2
Frequent bowel movements	1	1.3	1	1	2.4	1	2	1.6	2
General disorders and administration site conditions	9	11.3	11	3	7.1	3	12	9.8	14
Fatigue	6	7.5	7	2	4.8	2	8	6.6	9
Influenza like illness	3	3.8	4	0	0	0	3	2.5	4
Nervous system disorders	5	6.3	8	2	4.8	2	7	5.7	10
Headache	3	3.8	5	2	4.8	2	5	4.1	7

Table 6: Incidence of TEAE by maximum severity - IBS-C and IBS-D cohorts

Severity	EBX-102-02 N=80		Placebo N=42		Overall N=122	
Patients with at least one TEAE	Number patients	%	Number patients	%	Number patients	%
Mild	39	48.8	26	61.9	65	53.3
Moderate	14	17.5	4	9.5	18	14.8
Severe	3	3.8	1	2.4	4	3.3

Secondary outcomes:

Secondary outcome measures were based on the on the per protocol population.

Irritable Bowel Syndrome Symptom Severity Scale (IBS-SSS) change from baseline

Table 7: Summary of IBS-SSS total score and change from baseline over time - IBS-C cohort

IBS-C cohort		EBX-102-02		Placebo	
Visit	**Statistics**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**
IBS-SSS Total Scores					
Baseline	n	40	-	19	-
	Mean	296.0	-	327.4	-
	SD	69.4		71.1	
Dosing 2 (Week 1)	n	39	39	19	19
	Mean	229.0	-67.4	284.2	-43.2
	SD	103.8	80.2	100.4	65.6
Follow-up 1 (Week 3)	n	39	39	19	19
	Mean	226.2	-70.3	286.3	-41.1
	SD	115.1	96.6	94.7	84.3
Final Follow-up / EOS (Week 7)	n	40	40	18	18
	Mean	216.8	-79.3	271.7	-60.6
	SD	103.6	93.0	88.8	79.6

Table 8: Summary of IBS-SSS total score and change from baseline over time - IBS-D cohort

IBS-D cohort		EBX-102-02		Placebo	
Visit	**Statistics**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**
IBS-SSS Total Scores					
Baseline	n	39		21	
	Mean	310.0		288.6	
	SD	76.8		79.8	
Dosing 2 (Week 1)	n	39	39	21	21
	Mean	240.3	-69.7	253.3	-35.2
	SD	105.1	87.9	96.4	58.3
Follow-up 1 (Week 3)	n	37	37	21	21
	Mean	251.4	-56.2	237.1	-51.4
	SD	109.0	92.0	94.8	72.0
Final Follow-up / EOS (Week 7)	n	36	36	20	20
	Mean	246.7	-61.4	253.5	-38.0
	SD	123.2	92.2	111.5	76.0

Patient Assessment of Constipation Symptoms (PAC-SYM) change from baseline

Table 9: Summary of PAC-SYM total score and change from baseline - IBS-C cohort

IBS-C cohort		EBX-102-02		Placebo	
Visit	**Statistics**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**
Baseline	n	40		19	
	Mean	2.054		2.167	
	SD	0.5948		0.6707	
Dosing 2 (Week 1)	n	39	39	19	19
	Mean	1.448	-0.612	1.680	-0.487
	SD	0.5722	0.6500	0.6360	0.3195
Follow-up 1 (Week 3)	n	39	39	19	19
	Mean	1.474	-0.586	1.702	-0.465
	SD	0.6909	0.6678	0.6069	0.7912
Final Follow-up / EOS (Week 7)	n	40	40	19	19
	Mean	1.385	-0.669	1.741	-0.425
	SD	0.6315	0.6543	0.7146	0.7677

Change in Stool consistency from baseline

Table 10: Summary of proportion of days with BSFS type 1 or 2 or no movement, and change from baseline - IBS-C Cohort

IBS-C cohort		EBX-102-02		Placebo	
Visit	**Statistic**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
Baseline	n	38		18	
	Mean	0.81		0.82	
	SD	0.19		0.16	
Week 1	n	37	36	19	18
	Mean	0.63	-0.19	0.63	-0.18
	SD	0.29	0.26	0.32	0.33
Week 3	n	38	37	19	18
	Mean	0.52	-0.29	0.65	-0.13
	SD	0.32	0.28	0.34	0.32
Week 7	n	39	38	19	18
	Mean	0.50	-0.32	0.63	-0.17
	SD	0.34	0.31	0.25	0.19

Table 11: Summary of proportion of days with BSFS type 6 or 7 and change from baseline - IBS-D cohort

IBS–D cohort		EBX-102-02		Placebo	
Visit	**Statistic**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
Baseline	n	39		21	
	Mean	0.76		0.71	
	SD	0.21		0.27	
Week 1	n	39	39	21	21
	Mean	0.56	-0.20	0.49	-0.22
	SD	0.32	0.23	0.34	0.23
Week 3	n	39	39	20	20
	Mean	0.56	-0.21	0.44	-0.26
	SD	0.35	0.35	0.35	0.32
Week 7	n	33	33	19	19
	Mean	0.50	-0.26	0.44	-0.27
	SD	0.36	0.31	0.34	0.28

Change in stool frequency

Table 12: Weekly stool frequency and change from baseline - IBS-C cohort

IBS-C cohort		EBX-102-02		Placebo	
Visit	**Statistic**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
Baseline	n	38		18	
	Mean	6.9		5.6	
	SD	5.1		2.9	
Week 1	n	37	36	19	18
	Mean	7.8	1.2	6.5	0.7
	SD	4.8	3.2	3.0	2.4
Week 3	n	38	37	19	18
	Mean	7.2	1.1	6.9	1.1
	SD	4.2	3.7	3.0	2.8
Week 7	n	39	38	19	18
	Mean	7.3	0.5	7.1	1.4
	SD	4.0	3.1	4.3	2.6

Table 13: Weekly Stool frequency band change from baseline - IBS-D cohort

IBS-D cohort		EBX-102-02		Placebo	
Visit	**Statistic**	**Value**	**Change from baseline**	**Value**	**Change from baseline**
Baseline	n	39		21	
	Mean	16.83		17.26	
	SD	7.36		10.13	
Week 1	n	39	39	21	21
	Mean	15.14	-1.69	15.14	-2.11
	SD	7.43	3.74	11.00	6.12
Week 3	n	39	39	20	20
	Mean	14.62	-2.21	13.33	-3.78
	SD	6.56	4.23	10.33	7.33
Week 7	n	33	33	19	19
	Mean	13.33	-2.95	12.21	-5.18
	SD	6.73	4.49	4.73	8.03

IBS-SSS change in pain severity

Table 14: Summary of IBS-SSS change in pain severity from baseline over time – IBS-C cohort

IBS-C cohort		EBX-102-02		Placebo	
Visit	**Statistics**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**
IBS-SSS Pain Scores					
Baseline	n	40		19	
	Mean	31.275		36.474	
	SD	19.2580		21.4486	
Dosing 2 (Week 1)	n	39	39	19	19
	Mean	20.974	-10.487	31.474	-5.000
	SD	21.2795	15.8212	24.9808	15.8254
Follow-up 1 (Week 3)	n	39	39	19	19
	Mean	21.641	-9.821	32.526	-3.947
	SD	24.0038	18.8427	22.6970	19.2887
Final Follow-up / EOS (Week 7)	n	40	40	18	18
	Mean	18.575	-12.700	29.111	-8.722
	SD	19.8751	21.0716	25.4741	19.6792

Table 15: Summary of IBS-SSS change in pain severity from baseline over time – IBS-D cohort

IBS-D cohort		EBX-102-02		Placebo	
Visit	**Statistics**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**
IBS-SSS Pain Scores					
Baseline	n	39		21	
	Mean	36.692		24.429	
	SD	19.5167		20.3238	
Dosing 2 (Week 1)	n	39	39	21	21
	Mean	24.077	-12.615	26.667	2.238
	SD	22.0423	17.2224	28.0309	18.0912
Follow-up 1 (Week 3)	n	37	37	21	21
	Mean	27.216	-8.568	19.714	-4.714
	SD	24.0672	19.8348	22.2804	13.9109
Final Follow-up / EOS (Week 7)	n	36	36	20	20
	Mean	27.833	-7.583	24.450	0.300
	SD	28.1146	22.8740	24.9325	15.1487