

STATISTICAL REPORT

PROSPECT

version 1.0

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Full Study Title:

PROState Pathway Embedded Comparative Trial

Short Study title / Acronym:

**Imperial Prostate Study 3
IP3-PROSPECT**

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2 Baseline Characteristics

Table 2.1: Baseline Characteristics

Factor	Total N=139	N	Missing from eCRF N(%)
Age: mean (SD)	66.4 (7.4)	139	0
Age: median (IQR)	66.8 (60.6-72.8)	139	0
Ethnicity If you are unsure, please follow this link		139	0
White	116 (83.5%)		
Mixed / Multiple Ethnic Groups	2 (1.4%)		
Asian / Asian British	7 (5.0%)		
Black / African / Caribbean / Black British	4 (2.9%)		
Other Ethnic Group	5 (3.6%)		
Unknown	5 (3.6%)		
Does the patient have any relatives with prostate or breast cancer?		138	1
Yes	29 (21.0%)		
No	109 (79.0%)		
BMI: mean (SD)	26.31 (5.14)	102	37
BMI: median (IQR)	25.80 (24.00-29.30)	102	37
PSA value	6.41 (3.28)	138	1
PSA value	5.68 (4.20-7.54)	138	1
DRE		129	10
No	96 (74.4%)		
Yes- (but DRE result missing)	1 (0.8%)		
Yes-Abnormal	7 (5.4%)		
Yes-Evidence for Locally Advanced/Metastatic Disease	1 (0.8%)		
Yes-Normal	24 (18.6%)		
WHO Performance Status		138	1
0	125 (90.6%)		
1	10 (7.2%)		
2	3 (2.2%)		

Presented as mean (SD) and median (IQR) for continuous and N (%) for categorical variables

3 Urological History

Table 3.1: Urological History

Factor	N (%)
Has the patient ever been treated for a prostate condition?	
No	112 (80.6%)
Yes	26 (18.7%)
Missing from eCRF	1 (0.7%)
Has the patient ever been prescribed medication for symptoms of an enlarged prostate? ¹	
No	5 (19.2%)
Yes	21 (80.8%)
Missing from eCRF	0 (0.0%)
Alpha Blocker (Tamsulosin/Alfuzosin) ¹	
No	8 (30.8%)
Yes	18 (69.2%)
Missing from eCRF	0 (0.0%)
5-ARI (Finasteride/Dutasteride) ¹	
No	20 (76.9%)
Yes	6 (23.1%)
Missing from eCRF	0 (0.0%)
PDE Inhibitor (Cialis) ¹	
No	24 (92.3%)
Yes	2 (7.7%)
Missing from eCRF	0 (0.0%)
Has the patient ever been prescribed hormones for prostate cancer? ¹	
No	24 (92.3%)
Yes	2 (7.7%)
Missing from eCRF	0 (0.0%)
Has the patient ever had a surgical procedure for an enlarged prostate? ¹	
No	21 (80.8%)
Yes Other	1 (3.8%)
Yes TURP (Monopolar/Bipolar)	4 (15.4%)
Missing from eCRF	0 (0.0%)

¹Only for those patients who have ever been treated for a prostate condition (Question 1 is answered "Yes")

4 Medical History

Table 4.1: Medical History

Factor	N (%)
Does the patient have any other current medical problems to report?	
No	49 (100%)
Yes	89 (100%)
Number of medical problems/conditions reported	89 (100%)
1	29 (32.6%)
2	27 (30.3%)
3	19 (21.3%)
4	3 (3.4%)
5	5 (5.6%)
6	5 (5.6%)
7	1 (1.1%)
Body System Code	214 (100%)
1.Constitutional symptoms (e.g., fever, weight loss)	1 (0.5%)
2.Eyes	6 (2.8%)
3.Ears, Nose, Mouth, Throat	3 (1.4%)
4.Cardiovascular	79 (36.9%)
5.Respiratory	16 (7.5%)
6.Gastrointestinal	20 (9.3%)
7.Genitourinary	29 (13.6%)
8.Musculoskeletal	18 (8.4%)
9.Integumentary (skin and/or breast)	7 (3.3%)
10.Neurological	5 (2.3%)
11.Psychiatric	7 (3.3%)
12.Endocrine	14 (6.5%)
13.Hematologic/Lymphatic	5 (2.3%)
14.Allergic/Immunologic	4 (1.9%)

5 Acceptability and feasibility endpoints

5.1 Consented patients

Table 5.1: Proportion of patients who consented to inclusion in PROSPECT cohort out of total number of patients approached

	Approached	Consented	Consent rate (95% CI)
ASP	8	6	75.0% (34.9% to 96.8%)
CXH (ICHT)	192	79	41.1% (34.1% to 48.5%)
HH	145	45	31.0% (23.6% to 39.2%)
WM	39	9	23.1% (11.1% to 39.3%)
Total	384	139	36.2% (31.4% to 41.2%)

5.2 Approached patients

Table 5.2: Proportion of men approached to enter PROSPECT out of number of men referred to the participating centres for investigation of prostate cancer

	Referred	Approached	Approached rate (95% CI)
ASP	14	8	57.1% (28.9% to 82.3%)
CXH (ICHT)	230	192	83.5% (78.0% to 88.0%)
HH	179	145	81.0% (74.5% to 86.5%)
WM	39	39	100% (91.0% to 100%)*
Total	462	384	83.1% (79.4% to 86.4%)

* one-sided, 97.5% confidence interval

6 Patient reported outcomes (PROMS)

6.1 Summary of proportions of patients who responded and completed the questionnaires

Table 6.1: Summary of proportions of patients who responded and completed the questionnaires at each visit

Visit	Questionnaire	Responded	Completed
Visit 0 (Baseline)	EQ-5D-5L	109 78.4% (70.6% to 84.9%)	109 100% (96.7% to 100%)*
	EPIC26	110 79.1% (71.4% to 85.6%)	107 97.3% (92.2% to 99.4%)
	IPSS	109 78.4% (70.6% to 84.9%)	107 98.2% (93.5% to 99.8%)
	IIEF-15	107 77.0% (69.1% to 83.7%)	99 92.5% (85.8% to 96.7%)
Visit 1	EQ-5D-5L	96 69.1% (60.7% to 76.6%)	96 100% (96.2% to 100%)*
	EPIC26	96 69.1% (60.7% to 76.6%)	94 97.9% (92.7% to 99.7%)
	IPSS	97 69.8% (61.4% to 77.3%)	96 99.0% (94.4% to 99.97%)
	IIEF-15	96 69.1% (60.7% to 76.6%)	88 91.7% (84.2% to 96.3%)
Visit 2	EQ-5D-5L	95 68.3% (59.9% to 76.0%)	93 97.9% (92.6% to 99.7%)
	EPIC26	93 66.9% (58.4% to 74.6%)	87 93.5% (86.5% to 97.6%)
	IPSS	93 66.9% (58.4% to 74.6%)	92 99.0% (94.1% to 99.97%)
	IIEF-15	91 65.5% (56.9% to 73.3%)	86 94.5% (87.6% to 98.2%)
Visit 3	EQ-5D-5L	24 17.3% (11.4% to 24.6%)	24 100% (85.8% to 100%)*
	EPIC26	24 17.3% (11.4% to 24.6%)	22 91.7% (73.0% to 99.0%)
	IPSS	24 17.3% (11.4% to 24.6%)	23 95.8% (78.9% to 99.9%)
	IIEF-15	23 16.5% (10.8% to 23.7%)	20 87.0% (66.4% to 97.2%)

¹Proportions of patients who responded to the questionnaires out of the total number of patients consented to the trial

²Proportions of patients who completed the questionnaires out of those who responded

*one-sided, 97.5% confidence interval

6.2 EPIC Scores - Visit 0 (Baseline)

Table 6.2: EPIC questionnaire results at visit 0 (baseline)

	Total Responded N=110
Question 1: Over the past 4 weeks, how often have you leaked urine? (Choose on	
More than once a day	3 (2.7%)
About once a day	9 (8.2%)
More than once a week	6 (5.5%)
About once a week	10 (9.1%)
Rarely or never	82 (74.5%)
Question 2: Which of the following best describes your urinary control during	
No urinary control whatsoever	1 (0.9%)
Frequent dribbling	2 (1.8%)
Occasional dribbling	36 (32.7%)
Total Responded control	71 (64.5%)
Question 3: How many pads or adult diapers per day did you use to control lea	
2 pads per day	1 (0.9%)
1 pad per day	2 (1.8%)
None	107 (97.3%)
Dripping or leaking urine	
Moderate Problem	1 (0.9%)
Small Problem	7 (6.4%)
Very Small Problem	30 (27.3%)
No Problem	72 (65.5%)
Pain or burning on urination	
Moderate Problem	2 (1.8%)
Small Problem	3 (2.7%)
Very Small Problem	13 (11.8%)
No Problem	92 (83.6%)
Bleeding with urination	
Moderate Problem	2 (1.8%)
Small Problem	1 (0.9%)
Very Small Problem	2 (1.8%)
No Problem	105 (95.5%)
Weak urine stream or incomplete emptying	
Big Problem	6 (5.5%)
Moderate Problem	23 (21.1%)
Small Problem	16 (14.7%)
Very Small Problem	31 (28.4%)
No Problem	33 (30.3%)
Need to urinate frequently during the day	
Big Problem	7 (6.4%)
Moderate Problem	18 (16.5%)
Small Problem	25 (22.9%)
Very Small Problem	22 (20.2%)
No Problem	37 (33.9%)
Question 5: Overall, how big a problem has your urinary function been for you	
Big problem	3 (2.7%)
Moderate problem	14 (12.7%)
Small problem	27 (24.5%)
Very small problem	32 (29.1%)
No problem	34 (30.9%)
a. Urgency to have a bowel movement	
Big Problem	2 (1.8%)
Moderate Problem	3 (2.7%)
Small Problem	8 (7.3%)
Very Small Problem	19 (17.3%)

No Problem	78 (70.9%)
b. Increased frequency of bowel movements	
Big Problem	1 (0.9%)
Moderate Problem	2 (1.8%)
Small Problem	8 (7.3%)
Very Small Problem	11 (10.1%)
No Problem	87 (79.8%)
c. Losing control of your stools	
Moderate Problem	1 (0.9%)
Small Problem	1 (0.9%)
Very Small Problem	6 (5.5%)
No Problem	101 (92.7%)
d. Bloody stools	
Moderate Problem	1 (0.9%)
Very Small Problem	4 (3.7%)
No Problem	104 (95.4%)
e. Abdominal/Pelvic/Rectal pain	
Big Problem	1 (0.9%)
Moderate Problem	1 (0.9%)
Small Problem	1 (0.9%)
Very Small Problem	9 (8.3%)
No Problem	97 (89.0%)
Question 7: Overall, how big a problem have your bowel habits been for you dur	
Big problem	1 (0.9%)
Moderate problem	1 (0.9%)
Small problem	5 (4.5%)
Very small problem	19 (17.3%)
No problem	84 (76.4%)
a. Your ability to have an erection?	
Very poor to none	17 (15.7%)
Poor	16 (14.8%)
Fair	29 (26.9%)
Good	30 (27.8%)
Very good	16 (14.8%)
b. Your ability to reach orgasm (climax)?	
Very poor to none	14 (13.1%)
Poor	15 (14.0%)
Fair	27 (25.2%)
Good	31 (29.0%)
Very good	20 (18.7%)
Question 9: How would you describe the usual QUALITY of your erections during	
None at all	13 (12.1%)
Not firm enough for any sexual activity	10 (9.3%)
Firm enough for masturbation and foreplay only	31 (29.0%)
Firm enough for intercourse	53 (49.5%)
Question 10: How would you describe the FREQUENCY of your erections during the	
I NEVER had an erection when I wanted one	20 (18.5%)
I had an erection LESS THAN HALF the time I wanted one	8 (7.4%)
I had an erection ABOUT HALF the time I wanted one	13 (12.0%)
I had an erection MORE THAN HALF the time I wanted one	24 (22.2%)
I had an erection WHENEVER I wanted one	43 (39.8%)
Question 11: Overall, how would you rate your ability to function sexually dur	
Very poor	17 (15.9%)
Poor	19 (17.8%)
Fair	26 (24.3%)
Good	31 (29.0%)
Very good	14 (13.1%)
Question 12: Overall, how big a problem has your sexual function or lack of se	
Big problem	13 (12.0%)

Moderate problem	15 (13.9%)
Small problem	14 (13.0%)
Very small problem	17 (15.7%)
No problem	49 (45.4%)
a. Hot flashes	
Moderate problem	1 (0.9%)
Small problem	1 (0.9%)
Very small problem	4 (3.7%)
No problem	103 (94.5%)
b. Breast tenderness/enlargement	
Very small problem	3 (2.8%)
No problem	106 (97.2%)
c. Feeling depressed	
Big problem	3 (2.8%)
Moderate problem	5 (4.6%)
Small problem	9 (8.3%)
Very small problem	21 (19.3%)
No problem	71 (65.1%)
d. Lack of energy	
Big problem	5 (4.6%)
Moderate problem	5 (4.6%)
Small problem	20 (18.3%)
Very small problem	29 (26.6%)
No problem	50 (45.9%)
e. Change in body weight	
Big problem	3 (2.8%)
Moderate problem	5 (4.6%)
Small problem	6 (5.5%)
Very small problem	12 (11.0%)
No problem	83 (76.1%)

Data are presented as n (%).

	Records Available
Question 1: Over the past 4 weeks, how often have you leaked urine? (Choose on	110
Question 2: Which of the following best describes your urinary control during	110
Question 3: How many pads or adult diapers per day did you use to control lea	110
Dripping or leaking urine	110
Pain or burning on urination	110
Bleeding with urination	110
Weak urine stream or incomplete emptying	109
Need to urinate frequently during the day	109
Question 5: Overall, how big a problem has your urinary function been for you	110
a. Urgency to have a bowel movement	110
b. Increased frequency of bowel movements	109
c. Losing control of your stools	109
d. Bloody stools	109
e. Abdominal/Pelvic/Rectal pain	109
Question 7: Overall, how big a problem have your bowel habits been for you dur	110
a. Your ability to have an erection?	108
b. Your ability to reach orgasm (climax)?	107
Question 9: How would you describe the usual QUALITY of your erections during	107
Question 10: How would you describe the FREQUENCY of your erections during the	108
Question 11: Overall, how would you rate your ability to function sexually dur	107
Question 12: Overall, how big a problem has your sexual function or lack of se	108
a. Hot flashes	109
b. Breast tenderness/enlargement	109

c. Feeling depressed	109
d. Lack of energy	109
e. Change in body weight	109

6.3 EPIC Scores - Visit 1

Table 6.3: EPIC questionnaire results at visit 1

	Total Responded N=96
Question 1: Over the past 4 weeks, how often have you leaked urine? (Choose on	
More than once a day	4 (4%)
About once a day	7 (7%)
More than once a week	5 (5%)
About once a week	14 (15%)
Rarely or never	66 (69%)
Question 2: Which of the following best describes your urinary control during	
Frequent dribbling	3 (3%)
Occasional dribbling	41 (43%)
Total Responded control	52 (54%)
Question 3: How many pads or adult diapers per day did you use to control lea	
3 or more pads per day	1 (1%)
2 pads per day	3 (3%)
1 pad per day	4 (4%)
None	88 (92%)
Dripping or leaking urine	
Moderate Problem	7 (7%)
Small Problem	6 (6%)
Very Small Problem	30 (32%)
No Problem	52 (55%)
Pain or burning on urination	
Moderate Problem	7 (7%)
Small Problem	1 (1%)
Very Small Problem	6 (6%)
No Problem	82 (85%)
Bleeding with urination	
Moderate Problem	2 (2%)
Small Problem	5 (5%)
No Problem	89 (93%)
Weak urine stream or incomplete emptying	
Big Problem	2 (2%)
Moderate Problem	19 (20%)
Small Problem	16 (17%)
Very Small Problem	21 (22%)
No Problem	38 (40%)
Need to urinate frequently during the day	
Big Problem	5 (5%)
Moderate Problem	15 (16%)
Small Problem	22 (23%)
Very Small Problem	26 (27%)
No Problem	28 (29%)
Question 5: Overall, how big a problem has your urinary function been for you	
Big problem	1 (1%)
Moderate problem	18 (19%)
Small problem	21 (22%)
Very small problem	29 (30%)
No problem	27 (28%)
a. Urgency to have a bowel movement	
Big Problem	3 (3%)
Moderate Problem	4 (4%)
Small Problem	8 (8%)
Very Small Problem	17 (18%)
No Problem	64 (67%)

b. Increased frequency of bowel movements	
Big Problem	1 (1%)
Moderate Problem	6 (6%)
Small Problem	4 (4%)
Very Small Problem	16 (17%)
No Problem	69 (72%)
c. Losing control of your stools	
Moderate Problem	2 (2%)
Small Problem	2 (2%)
Very Small Problem	5 (5%)
No Problem	86 (91%)
d. Bloody stools	
Very Small Problem	2 (2%)
No Problem	94 (98%)
e. Abdominal/Pelvic/Rectal pain	
Big Problem	1 (1%)
Moderate Problem	2 (2%)
Small Problem	3 (3%)
Very Small Problem	6 (6%)
No Problem	84 (88%)
Question 7: Overall, how big a problem have your bowel habits been for you dur	
Big problem	2 (2%)
Moderate problem	4 (4%)
Small problem	10 (10%)
Very small problem	11 (11%)
No problem	69 (72%)
a. Your ability to have an erection?	
Very poor to none	24 (26%)
Poor	17 (18%)
Fair	18 (19%)
Good	24 (26%)
Very good	11 (12%)
b. Your ability to reach orgasm (climax)?	
Very poor to none	28 (30%)
Poor	9 (10%)
Fair	19 (20%)
Good	23 (24%)
Very good	15 (16%)
Question 9: How would you describe the usual QUALITY of your erections during	
None at all	18 (19%)
Not firm enough for any sexual activity	15 (16%)
Firm enough for masturbation and foreplay only	19 (20%)
Firm enough for intercourse	42 (45%)
Question 10: How would you describe the FREQUENCY of your erections during the	
I NEVER had an erection when I wanted one	23 (24%)
I had an erection LESS THAN HALF the time I wanted one	12 (13%)
I had an erection ABOUT HALF the time I wanted one	12 (13%)
I had an erection MORE THAN HALF the time I wanted one	17 (18%)
I had an erection WHENEVER I wanted one	30 (32%)
Question 11: Overall, how would you rate your ability to function sexually dur	
Very poor	29 (31%)
Poor	16 (17%)
Fair	13 (14%)
Good	26 (28%)
Very good	10 (11%)
Question 12: Overall, how big a problem has your sexual function or lack of se	
Big problem	11 (12%)
Moderate problem	13 (14%)
Small problem	11 (12%)

Very small problem	16 (17%)
No problem	44 (46%)
a. Hot flashes	
Big problem	1 (1%)
Moderate problem	4 (4%)
Small problem	3 (3%)
Very small problem	1 (1%)
No problem	86 (91%)
b. Breast tenderness/enlargement	
Moderate problem	1 (1%)
Very small problem	2 (2%)
No problem	93 (97%)
c. Feeling depressed	
Big problem	4 (4%)
Moderate problem	5 (5%)
Small problem	10 (10%)
Very small problem	11 (11%)
No problem	66 (69%)
d. Lack of energy	
Big problem	4 (4%)
Moderate problem	13 (14%)
Small problem	13 (14%)
Very small problem	23 (24%)
No problem	43 (45%)
e. Change in body weight	
Big problem	3 (3%)
Moderate problem	2 (2%)
Small problem	7 (7%)
Very small problem	13 (14%)
No problem	70 (74%)

Data are presented as n (%).

	Records Available
Question 1: Over the past 4 weeks, how often have you leaked urine? (Choose on	96
Question 2: Which of the following best describes your urinary control during	96
Question 3: How many pads or adult diapers per day did you use to control lea	96
Dripping or leaking urine	95
Pain or burning on urination	96
Bleeding with urination	96
Weak urine stream or incomplete emptying	96
Need to urinate frequently during the day	96
Question 5: Overall, how big a problem has your urinary function been for you	96
a. Urgency to have a bowel movement	96
b. Increased frequency of bowel movements	96
c. Losing control of your stools	95
d. Bloody stools	96
e. Abdominal/Pelvic/Rectal pain	96
Question 7: Overall, how big a problem have your bowel habits been for you dur	96
a. Your ability to have an erection?	94
b. Your ability to reach orgasm (climax)?	94
Question 9: How would you describe the usual QUALITY of your erections during	94
Question 10: How would you describe the FREQUENCY of your erections during the	94
Question 11: Overall, how would you rate your ability to function sexually dur	94
Question 12: Overall, how big a problem has your sexual function or lack of se	95

a. Hot flashes	95
b. Breast tenderness/enlargement	96
c. Feeling depressed	96
d. Lack of energy	96
e. Change in body weight	95

6.4 EPIC Scores - Visit 2

Table 6.4: EPIC questionnaire results at visit 2

	Total Responded N=93
Question 1: Over the past 4 weeks, how often have you leaked urine? (Choose on	
More than once a day	5 (5%)
About once a day	8 (9%)
More than once a week	5 (5%)
About once a week	11 (12%)
Rarely or never	64 (69%)
Question 2: Which of the following best describes your urinary control during	
Frequent dribbling	4 (4%)
Occasional dribbling	38 (41%)
Total Responded control	51 (55%)
Question 3: How many pads or adult diapers per day did you use to control lea	
3 or more pads per day	1 (1%)
2 pads per day	1 (1%)
1 pad per day	4 (4%)
None	87 (94%)
Dripping or leaking urine	
Big Problem	1 (1%)
Moderate Problem	5 (5%)
Small Problem	13 (14%)
Very Small Problem	18 (19%)
No Problem	56 (60%)
Pain or burning on urination	
Big Problem	1 (1%)
Moderate Problem	3 (3%)
Small Problem	2 (2%)
Very Small Problem	8 (9%)
No Problem	78 (85%)
Bleeding with urination	
Very Small Problem	3 (3%)
No Problem	89 (97%)
Weak urine stream or incomplete emptying	
Big Problem	5 (5%)
Moderate Problem	9 (10%)
Small Problem	14 (15%)
Very Small Problem	26 (29%)
No Problem	37 (41%)
Need to urinate frequently during the day	
Big Problem	6 (7%)
Moderate Problem	14 (15%)
Small Problem	15 (16%)
Very Small Problem	25 (27%)
No Problem	32 (35%)
Question 5: Overall, how big a problem has your urinary function been for you	
Big problem	3 (3%)
Moderate problem	14 (15%)
Small problem	14 (15%)
Very small problem	23 (25%)
No problem	39 (42%)
a. Urgency to have a bowel movement	
Big Problem	1 (1%)
Moderate Problem	2 (2%)
Small Problem	9 (10%)
Very Small Problem	25 (27%)

No Problem	56 (60%)
b. Increased frequency of bowel movements	
Big Problem	1 (1%)
Moderate Problem	3 (3%)
Small Problem	7 (8%)
Very Small Problem	15 (16%)
No Problem	67 (72%)
c. Losing control of your stools	
Small Problem	2 (2%)
Very Small Problem	8 (9%)
No Problem	83 (89%)
d. Bloody stools	
Big Problem	1 (1%)
Very Small Problem	2 (2%)
No Problem	90 (97%)
e. Abdominal/Pelvic/Rectal pain	
Moderate Problem	1 (1%)
Small Problem	1 (1%)
Very Small Problem	8 (9%)
No Problem	81 (89%)
Question 7: Overall, how big a problem have your bowel habits been for you dur	
Big problem	1 (1%)
Moderate problem	3 (3%)
Small problem	2 (2%)
Very small problem	22 (24%)
No problem	65 (70%)
a. Your ability to have an erection?	
Very poor to none	27 (31%)
Poor	17 (19%)
Fair	16 (18%)
Good	20 (23%)
Very good	8 (9%)
b. Your ability to reach orgasm (climax)?	
Very poor to none	22 (25%)
Poor	15 (17%)
Fair	18 (21%)
Good	25 (29%)
Very good	7 (8%)
Question 9: How would you describe the usual QUALITY of your erections during	
None at all	22 (25%)
Not firm enough for any sexual activity	13 (15%)
Firm enough for masturbation and foreplay only	24 (27%)
Firm enough for intercourse	29 (33%)
Question 10: How would you describe the FREQUENCY of your erections during the	
I NEVER had an erection when I wanted one	28 (31%)
I had an erection LESS THAN HALF the time I wanted one	10 (11%)
I had an erection ABOUT HALF the time I wanted one	11 (12%)
I had an erection MORE THAN HALF the time I wanted one	19 (21%)
I had an erection WHENEVER I wanted one	21 (24%)
Question 11: Overall, how would you rate your ability to function sexually dur	
Very poor	32 (36%)
Poor	13 (15%)
Fair	19 (22%)
Good	19 (22%)
Very good	5 (6%)
Question 12: Overall, how big a problem has your sexual function or lack of se	
Big problem	10 (11%)
Moderate problem	15 (17%)
Small problem	12 (13%)

Very small problem	18 (20%)
No problem	34 (38%)
a. Hot flashes	
Big problem	1 (1%)
Moderate problem	2 (2%)
Small problem	2 (2%)
Very small problem	3 (3%)
No problem	85 (91%)
b. Breast tenderness/enlargement	
Moderate problem	2 (2%)
Small problem	3 (3%)
No problem	86 (95%)
c. Feeling depressed	
Big problem	1 (1%)
Moderate problem	5 (5%)
Small problem	12 (13%)
Very small problem	20 (22%)
No problem	54 (59%)
d. Lack of energy	
Big problem	1 (1%)
Moderate problem	17 (18%)
Small problem	17 (18%)
Very small problem	25 (27%)
No problem	33 (35%)
e. Change in body weight	
Moderate problem	7 (8%)
Small problem	7 (8%)
Very small problem	12 (13%)
No problem	66 (72%)

Data are presented as n (%).

	Records Available
Question 1: Over the past 4 weeks, how often have you leaked urine? (Choose on	93
Question 2: Which of the following best describes your urinary control during	93
Question 3: How many pads or adult diapers per day did you use to control lea	93
Dripping or leaking urine	93
Pain or burning on urination	92
Bleeding with urination	92
Weak urine stream or incomplete emptying	91
Need to urinate frequently during the day	92
Question 5: Overall, how big a problem has your urinary function been for you	93
a. Urgency to have a bowel movement	93
b. Increased frequency of bowel movements	93
c. Losing control of your stools	93
d. Bloody stools	93
e. Abdominal/Pelvic/Rectal pain	91
Question 7: Overall, how big a problem have your bowel habits been for you dur	93
a. Your ability to have an erection?	88
b. Your ability to reach orgasm (climax)?	87
Question 9: How would you describe the usual QUALITY of your erections during	88
Question 10: How would you describe the FREQUENCY of your erections during the	89
Question 11: Overall, how would you rate your ability to function sexually dur	88
Question 12: Overall, how big a problem has your sexual function or lack of se	89
a. Hot flashes	93

b. Breast tenderness/enlargement	91
c. Feeling depressed	92
d. Lack of energy	93
e. Change in body weight	92

6.5 EPIC Scores - Visit 3

Table 6.5: EPIC questionnaire results at visit 3

	Total Responded N=24
Question 1: Over the past 4 weeks, how often have you leaked urine? (Choose on	
More than once a day	1 (4%)
About once a day	2 (8%)
About once a week	4 (17%)
Rarely or never	17 (71%)
Question 2: Which of the following best describes your urinary control during	
Occasional dribbling	9 (38%)
Total Responded control	15 (63%)
Question 3: How many pads or adult diapers per day did you use to control lea	
None	24 (100%)
Dripping or leaking urine	
Moderate Problem	1 (4%)
Small Problem	1 (4%)
Very Small Problem	7 (30%)
No Problem	14 (61%)
Pain or burning on urination	
Very Small Problem	4 (17%)
No Problem	20 (83%)
Bleeding with urination	
No Problem	24 (100%)
Weak urine stream or incomplete emptying	
Moderate Problem	1 (4%)
Small Problem	6 (25%)
Very Small Problem	5 (21%)
No Problem	12 (50%)
Need to urinate frequently during the day	
Moderate Problem	1 (4%)
Small Problem	5 (21%)
Very Small Problem	7 (29%)
No Problem	11 (46%)
Question 5: Overall, how big a problem has your urinary function been for you	
Moderate problem	4 (17%)
Small problem	1 (4%)
Very small problem	9 (38%)
No problem	10 (42%)
a. Urgency to have a bowel movement	
Moderate Problem	1 (4%)
Small Problem	1 (4%)
Very Small Problem	1 (4%)
No Problem	21 (88%)
b. Increased frequency of bowel movements	
Small Problem	1 (4%)
No Problem	23 (96%)
c. Losing control of your stools	
No Problem	24 (100%)
d. Bloody stools	
Very Small Problem	1 (4%)
No Problem	23 (96%)
e. Abdominal/Pelvic/Rectal pain	
Very Small Problem	1 (4%)
No Problem	23 (96%)
Question 7: Overall, how big a problem have your bowel habits been for you dur	
Small problem	1 (4%)

Very small problem	1 (4%)
No problem	22 (92%)
a. Your ability to have an erection?	
Very poor to none	5 (22%)
Poor	5 (22%)
Fair	4 (17%)
Good	6 (26%)
Very good	3 (13%)
b. Your ability to reach orgasm (climax)?	
Very poor to none	4 (18%)
Poor	4 (18%)
Fair	3 (14%)
Good	5 (23%)
Very good	6 (27%)
Question 9: How would you describe the usual QUALITY of your erections during	
None at all	4 (18%)
Not firm enough for any sexual activity	2 (9%)
Firm enough for masturbation and foreplay only	7 (32%)
Firm enough for intercourse	9 (41%)
Question 10: How would you describe the FREQUENCY of your erections during the	
I NEVER had an erection when I wanted one	6 (27%)
I had an erection LESS THAN HALF the time I wanted one	1 (5%)
I had an erection ABOUT HALF the time I wanted one	3 (14%)
I had an erection MORE THAN HALF the time I wanted one	5 (23%)
I had an erection WHENEVER I wanted one	7 (32%)
Question 11: Overall, how would you rate your ability to function sexually dur	
Very poor	5 (23%)
Poor	4 (18%)
Fair	4 (18%)
Good	6 (27%)
Very good	3 (14%)
Question 12: Overall, how big a problem has your sexual function or lack of se	
Big problem	1 (5%)
Moderate problem	3 (14%)
Small problem	4 (18%)
Very small problem	4 (18%)
No problem	10 (45%)
a. Hot flashes	
Very small problem	2 (8%)
No problem	22 (92%)
b. Breast tenderness/enlargement	
No problem	24 (100%)
c. Feeling depressed	
Small problem	4 (17%)
Very small problem	7 (29%)
No problem	13 (54%)
d. Lack of energy	
Moderate problem	1 (4%)
Small problem	2 (8%)
Very small problem	13 (54%)
No problem	8 (33%)
e. Change in body weight	
Big problem	1 (4%)
Very small problem	6 (25%)
No problem	17 (71%)

Data are presented as n (%).

	Records Available
Question 1: Over the past 4 weeks, how often have you leaked urine? (Choose on	24
Question 2: Which of the following best describes your urinary control during	24
Question 3: How many pads or adult diapers per day did you use to control lea	24
Dripping or leaking urine	23
Pain or burning on urination	24
Bleeding with urination	24
Weak urine stream or incomplete emptying	24
Need to urinate frequently during the day	24
Question 5: Overall, how big a problem has your urinary function been for you	24
a. Urgency to have a bowel movement	24
b. Increased frequency of bowel movements	24
c. Losing control of your stools	24
d. Bloody stools	24
e. Abdominal/Pelvic/Rectal pain	24
Question 7: Overall, how big a problem have your bowel habits been for you dur	24
a. Your ability to have an erection?	23
b. Your ability to reach orgasm (climax)?	22
Question 9: How would you describe the usual QUALITY of your erections during	22
Question 10: How would you describe the FREQUENCY of your erections during the	22
Question 11: Overall, how would you rate your ability to function sexually dur	22
Question 12: Overall, how big a problem has your sexual function or lack of se	22
a. Hot flashes	24
b. Breast tenderness/enlargement	24
c. Feeling depressed	24
d. Lack of energy	24
e. Change in body weight	24

6.6 IPSS Scores - Visit 0 (Baseline)

Table 6.6: IPSS questionnaire results at visit 0 (baseline)

	Total Responded N=109
Over the past month or so, how often have you had a sensation of not emptying yo	1.57 (1.60)
During the past month or so, how often have you had to urinate again less than t	2.27 (1.51)
During the past month or so, how often have you found you stopped and started ag	1.46 (1.58)
During the past month or so, how often have you found it difficult to postpone u	1.35 (1.49)
During the past month or so, how often have you had a weak urinary stream?	1.93 (1.75)
During the past month or so, how often have you had to push or strain to begin u	0.89 (1.39)
Over the past month, how many times per night did you most typically get up to u	1.75 (1.33)
How would you feel if you had to live with your urinary condition the way it is	2.39 (1.56)

Data are presented as mean (SD).

	Records Available
Over the past month or so, how often have you had a sensation of not emptying yo	108
During the past month or so, how often have you had to urinate again less than t	109
During the past month or so, how often have you found you stopped and started ag	109
During the past month or so, how often have you found it difficult to postpone u	109
During the past month or so, how often have you had a weak urinary stream?	109
During the past month or so, how often have you had to push or strain to begin u	107
Over the past month, how many times per night did you most typically get up to u	109
How would you feel if you had to live with your urinary condition the way it is	109

6.7 IPSS Scores - Visit 1

Table 6.7: IPSS questionnaire results at visit 1

	Total Responded N=97
Over the past month or so, how often have you had a sensation of not emptying yo	1.55 (1.50)
During the past month or so, how often have you had to urinate again less than t	2.23 (1.52)
During the past month or so, how often have you found you stopped and started ag	1.59 (1.64)
During the past month or so, how often have you found it difficult to postpone u	1.54 (1.55)
During the past month or so, how often have you had a weak urinary stream?	1.90 (1.66)
During the past month or so, how often have you had to push or strain to begin u	0.84 (1.30)
Over the past month, how many times per night did you most typically get up to u	1.91 (1.21)
How would you feel if you had to live with your urinary condition the way it is	2.44 (1.63)

Data are presented as mean (SD).

	Records Available
Over the past month or so, how often have you had a sensation of not emptying yo	96
During the past month or so, how often have you had to urinate again less than t	97
During the past month or so, how often have you found you stopped and started ag	97
During the past month or so, how often have you found it difficult to postpone u	97
During the past month or so, how often have you had a weak urinary stream?	97
During the past month or so, how often have you had to push or strain to begin u	97
Over the past month, how many times per night did you most typically get up to u	96
How would you feel if you had to live with your urinary condition the way it is	97

6.8 IPSS Scores - Visit 2

Table 6.8: IPSS questionnaire results at visit 2

	Total Responded N=93
Over the past month or so, how often have you had a sensation of not emptying yo	1.38 (1.50)
During the past month or so, how often have you had to urinate again less than t	2.08 (1.51)
During the past month or so, how often have you found you stopped and started ag	1.43 (1.62)
During the past month or so, how often have you found it difficult to postpone u	1.74 (1.67)
During the past month or so, how often have you had a weak urinary stream?	1.66 (1.60)
During the past month or so, how often have you had to push or strain to begin u	0.61 (1.05)
Over the past month, how many times per night did you most typically get up to u	1.87 (1.34)
How would you feel if you had to live with your urinary condition the way it is	2.25 (1.56)

Data are presented as mean (SD).

	Records Available
Over the past month or so, how often have you had a sensation of not emptying yo	92
During the past month or so, how often have you had to urinate again less than t	92
During the past month or so, how often have you found you stopped and started ag	93
During the past month or so, how often have you found it difficult to postpone u	92
During the past month or so, how often have you had a weak urinary stream?	92
During the past month or so, how often have you had to push or strain to begin u	93
Over the past month, how many times per night did you most typically get up to u	93
How would you feel if you had to live with your urinary condition the way it is	92

6.9 IPSS Scores - Visit 3

Table 6.9: IPSS questionnaire results at visit 3

	Total Responded N=24
Over the past month or so, how often have you had a sensation of not emptying yo	1.17 (1.31)
During the past month or so, how often have you had to urinate again less than t	1.92 (1.18)
During the past month or so, how often have you found you stopped and started ag	1.08 (1.10)
During the past month or so, how often have you found it difficult to postpone u	1.26 (1.21)
During the past month or so, how often have you had a weak urinary stream?	1.42 (1.61)
During the past month or so, how often have you had to push or strain to begin u	0.67 (1.05)
Over the past month, how many times per night did you most typically get up to u	1.63 (1.21)
How would you feel if you had to live with your urinary condition the way it is	2.13 (1.54)

Data are presented as mean (SD).

	Records Available
Over the past month or so, how often have you had a sensation of not emptying yo	24
During the past month or so, how often have you had to urinate again less than t	24
During the past month or so, how often have you found you stopped and started ag	24
During the past month or so, how often have you found it difficult to postpone u	23
During the past month or so, how often have you had a weak urinary stream?	24
During the past month or so, how often have you had to push or strain to begin u	24
Over the past month, how many times per night did you most typically get up to u	24
How would you feel if you had to live with your urinary condition the way it is	24

6.10 IIEF Scores - Visit 0 (Baseline)

Table 6.10: IIEF questionnaire results at visit 0 (Baseline)

	Total Responded N=107
Questions 1: How often were you able to get an erection during sexual activity?	2.89 (2.09)
Questions 2: When you had erections with sexual stimulation, how often were you	2.72 (2.04)
Question 3: When you attempted intercourse, how often were you able to penetrat	2.24 (2.21)
Question 4: During sexual intercourse, how often were you able to maintain your	2.16 (2.16)
Question 5: During sexual intercourse, how difficult was it to maintain your er	2.30 (2.22)
Question 6: How many times have you attempted sexual intercourse?	1.15 (1.52)
Question 7: When you attempted sexual intercourse, how often was it satisfactor	1.90 (2.19)
Question 8: How much have you enjoyed sexual intercourse?	1.98 (2.15)
Question 9: When you had sexual stimulation or intercourse, how often did you e	3.20 (2.05)
Question 10: When you had sexual stimulation or intercourse, how often did you	3.60 (1.68)
Question 11: How often have you felt sexual desire?	3.32 (1.30)
Question 12: How would you rate your level of sexual desire?	2.92 (0.97)
Question 13: How satisfied have you been with your overall sex life?	3.10 (1.41)
Question 14: How satisfied have you been with your sexual relationship with you	3.16 (1.58)
Question 15: How do you rate your confidence that you could get and keep an ere	2.97 (1.40)

Data are presented as mean (SD).

	Records Available
Questions 1: How often were you able to get an erection during sexual activity?	107
Questions 2: When you had erections with sexual stimulation, how often were you	106
Question 3: When you attempted intercourse, how often were you able to penetrat	106
Question 4: During sexual intercourse, how often were you able to maintain your	106
Question 5: During sexual intercourse, how difficult was it to maintain your er	105
Question 6: How many times have you attempted sexual intercourse?	104
Question 7: When you attempted sexual intercourse, how often was it satisfactor	104
Question 8: How much have you enjoyed sexual intercourse?	104
Question 9: When you had sexual stimulation or intercourse, how often did you e	104
Question 10: When you had sexual stimulation or intercourse, how often did you	102
Question 11: How often have you felt sexual desire?	102
Question 12: How would you rate your level of sexual desire?	102
Question 13: How satisfied have you been with your overall sex life?	102
Question 14: How satisfied have you been with your sexual relationship with you	99
Question 15: How do you rate your confidence that you could get and keep an ere	103

6.11 IIEF Scores - Visit 1

Table 6.11: IIEF questionnaire results at visit 1

	Total Responded N=96
Questions 1: How often were you able to get an erection during sexual activity?	2.38 (2.19)
Questions 2: When you had erections with sexual stimulation, how often were you	2.27 (2.18)
Question 3: When you attempted intercourse, how often were you able to penetrat	1.98 (2.18)
Question 4: During sexual intercourse, how often were you able to maintain your	1.88 (2.15)
Question 5: During sexual intercourse, how difficult was it to maintain your er	1.88 (2.15)
Question 6: How many times have you attempted sexual intercourse?	0.99 (1.28)
Question 7: When you attempted sexual intercourse, how often was it satisfactor	1.83 (2.15)
Question 8: How much have you enjoyed sexual intercourse?	1.83 (2.00)
Question 9: When you had sexual stimulation or intercourse, how often did you e	2.59 (2.26)
Question 10: When you had sexual stimulation or intercourse, how often did you	3.26 (1.75)
Question 11: How often have you felt sexual desire?	2.94 (1.37)
Question 12: How would you rate your level of sexual desire?	2.77 (1.17)
Question 13: How satisfied have you been with your overall sex life?	2.92 (1.42)
Question 14: How satisfied have you been with your sexual relationship with you	2.92 (1.43)
Question 15: How do you rate your confidence that you could get and keep an ere	2.79 (1.46)

Data are presented as mean (SD).

	Records Available
Questions 1: How often were you able to get an erection during sexual activity?	96
Questions 2: When you had erections with sexual stimulation, how often were you	95
Question 3: When you attempted intercourse, how often were you able to penetrat	95
Question 4: During sexual intercourse, how often were you able to maintain your	96
Question 5: During sexual intercourse, how difficult was it to maintain your er	95
Question 6: How many times have you attempted sexual intercourse?	95
Question 7: When you attempted sexual intercourse, how often was it satisfactor	95
Question 8: How much have you enjoyed sexual intercourse?	94
Question 9: When you had sexual stimulation or intercourse, how often did you e	93
Question 10: When you had sexual stimulation or intercourse, how often did you	90
Question 11: How often have you felt sexual desire?	93
Question 12: How would you rate your level of sexual desire?	92
Question 13: How satisfied have you been with your overall sex life?	93
Question 14: How satisfied have you been with your sexual relationship with you	88
Question 15: How do you rate your confidence that you could get and keep an ere	92

6.12 IIEF Scores - Visit 2

Table 6.12: IIEF questionnaire results at visit 2

	Total Responded N=91
Questions 1: How often were you able to get an erection during sexual activity?	2.03 (2.07)
Questions 2: When you had erections with sexual stimulation, how often were you	1.87 (2.06)
Question 3: When you attempted intercourse, how often were you able to penetrat	1.62 (2.03)
Question 4: During sexual intercourse, how often were you able to maintain your	1.57 (2.04)
Question 5: During sexual intercourse, how difficult was it to maintain your er	1.70 (2.13)
Question 6: How many times have you attempted sexual intercourse?	1.00 (1.38)
Question 7: When you attempted sexual intercourse, how often was it satisfactor	1.64 (2.05)
Question 8: How much have you enjoyed sexual intercourse?	1.67 (1.94)
Question 9: When you had sexual stimulation or intercourse, how often did you e	2.72 (2.13)
Question 10: When you had sexual stimulation or intercourse, how often did you	3.23 (1.71)
Question 11: How often have you felt sexual desire?	2.87 (1.32)
Question 12: How would you rate your level of sexual desire?	2.69 (1.21)
Question 13: How satisfied have you been with your overall sex life?	2.66 (1.37)
Question 14: How satisfied have you been with your sexual relationship with you	3.05 (1.40)
Question 15: How do you rate your confidence that you could get and keep an ere	2.59 (1.39)

Data are presented as mean (SD).

	Records Available
Questions 1: How often were you able to get an erection during sexual activity?	91
Questions 2: When you had erections with sexual stimulation, how often were you	91
Question 3: When you attempted intercourse, how often were you able to penetrat	91
Question 4: During sexual intercourse, how often were you able to maintain your	91
Question 5: During sexual intercourse, how difficult was it to maintain your er	89
Question 6: How many times have you attempted sexual intercourse?	90
Question 7: When you attempted sexual intercourse, how often was it satisfactor	91
Question 8: How much have you enjoyed sexual intercourse?	91
Question 9: When you had sexual stimulation or intercourse, how often did you e	90
Question 10: When you had sexual stimulation or intercourse, how often did you	88
Question 11: How often have you felt sexual desire?	91
Question 12: How would you rate your level of sexual desire?	91
Question 13: How satisfied have you been with your overall sex life?	89
Question 14: How satisfied have you been with your sexual relationship with you	86
Question 15: How do you rate your confidence that you could get and keep an ere	87

6.13 IIEF Scores - Visit 3

Table 6.13: IIEF questionnaire results at visit 3

	Total Responded N=23
Questions 1: How often were you able to get an erection during sexual activity?	2.74 (2.07)
Questions 2: When you had erections with sexual stimulation, how often were you	2.35 (2.21)
Question 3: When you attempted intercourse, how often were you able to penetrat	2.27 (2.27)
Question 4: During sexual intercourse, how often were you able to maintain your	2.18 (2.24)
Question 5: During sexual intercourse, how difficult was it to maintain your er	2.18 (2.24)
Question 6: How many times have you attempted sexual intercourse?	1.36 (1.56)
Question 7: When you attempted sexual intercourse, how often was it satisfactor	2.29 (2.26)
Question 8: How much have you enjoyed sexual intercourse?	2.24 (2.12)
Question 9: When you had sexual stimulation or intercourse, how often did you e	3.48 (1.99)
Question 10: When you had sexual stimulation or intercourse, how often did you	3.90 (1.55)
Question 11: How often have you felt sexual desire?	3.09 (1.15)
Question 12: How would you rate your level of sexual desire?	2.82 (1.05)
Question 13: How satisfied have you been with your overall sex life?	3.29 (1.19)
Question 14: How satisfied have you been with your sexual relationship with you	3.40 (1.31)
Question 15: How do you rate your confidence that you could get and keep an ere	2.77 (1.34)

Data are presented as mean (SD).

	Records Available
Questions 1: How often were you able to get an erection during sexual activity?	23
Questions 2: When you had erections with sexual stimulation, how often were you	23
Question 3: When you attempted intercourse, how often were you able to penetrat	22
Question 4: During sexual intercourse, how often were you able to maintain your	22
Question 5: During sexual intercourse, how difficult was it to maintain your er	22
Question 6: How many times have you attempted sexual intercourse?	22
Question 7: When you attempted sexual intercourse, how often was it satisfactor	21
Question 8: How much have you enjoyed sexual intercourse?	21
Question 9: When you had sexual stimulation or intercourse, how often did you e	21
Question 10: When you had sexual stimulation or intercourse, how often did you	21
Question 11: How often have you felt sexual desire?	22
Question 12: How would you rate your level of sexual desire?	22
Question 13: How satisfied have you been with your overall sex life?	21
Question 14: How satisfied have you been with your sexual relationship with you	20
Question 15: How do you rate your confidence that you could get and keep an ere	22

6.14 EQ5D-5L Scores - Visit 0 (Baseline)

Table 6.14: EQ5D-5L questionnaire results at visit 0 (baseline)

	Total Responded N=109
MOBILITY	1.32 (0.65)
SELF-CARE	1.05 (0.21)
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	1.22 (0.52)
PAIN / DISCOMFORT	1.47 (0.71)
ANXIETY / DEPRESSION	1.43 (0.71)
We would like to know how good or bad your health is TODAY. This scale is numb	79.20 (14.68)

Data are presented as mean (SD).

	Records Available
MOBILITY	109
SELF-CARE	109
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	109
PAIN / DISCOMFORT	109
ANXIETY / DEPRESSION	109
We would like to know how good or bad your health is TODAY. This scale is numb	109

6.15 EQ5D-5L Scores - Visit 1

Table 6.15: EQ5D-5L questionnaire results at visit 1

	Total Responded N=96
MOBILITY	1.30 (0.68)
SELF-CARE	1.06 (0.24)
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	1.33 (0.63)
PAIN / DISCOMFORT	1.63 (0.78)
ANXIETY / DEPRESSION	1.51 (0.81)
We would like to know how good or bad your health is TODAY. This scale is numb	75.80 (17.63)

Data are presented as mean (SD).

	Records Available
MOBILITY	96
SELF-CARE	96
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	96
PAIN / DISCOMFORT	96
ANXIETY / DEPRESSION	96
We would like to know how good or bad your health is TODAY. This scale is numb	96

6.16 EQ5D-5L Scores - Visit 2

Table 6.16: EQ5D-5L questionnaire results at visit 2

	Total Responded N=95
MOBILITY	1.29 (0.62)
SELF-CARE	1.09 (0.32)
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	1.27 (0.57)
PAIN / DISCOMFORT	1.56 (0.65)
ANXIETY / DEPRESSION	1.44 (0.63)
We would like to know how good or bad your health is TODAY. This scale is numb	76.18 (16.35)

Data are presented as mean (SD).

	Records Available
MOBILITY	93
SELF-CARE	93
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	93
PAIN / DISCOMFORT	93
ANXIETY / DEPRESSION	93
We would like to know how good or bad your health is TODAY. This scale is numb	95

6.17 EQ5D-5L Scores - Visit 3

Table 6.17: EQ5D-5L questionnaire results at visit 3

	Total Responded N=24
MOBILITY	1.29 (0.86)
SELF-CARE	1.17 (0.56)
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	1.29 (0.62)
PAIN / DISCOMFORT	1.46 (0.78)
ANXIETY / DEPRESSION	1.42 (0.50)
We would like to know how good or bad your health is TODAY. This scale is numb	78.25 (17.45)

Data are presented as mean (SD).

	Records Available
MOBILITY	24
SELF-CARE	24
USUAL ACTIVITIES (e.g. work, study, housework, family or leisure activities)	24
PAIN / DISCOMFORT	24
ANXIETY / DEPRESSION	24
We would like to know how good or bad your health is TODAY. This scale is numb	24

7 Disease characteristics and treatment data

7.1 Visit 1

	N (%)	Records Available
Since the last visit, has the patient been diagnosed with any new medical condition?		138
No	118 (85.5%)	
Yes	20 (14.5%)	
Was a diagnostic prostate MRI performed?		137
No	6 (4.4%)	
Yes	131 (95.6%)	
Prostate Volume	55.9 (27.7)	128
Number of Lesions Identified on MRI		130
0	48 (36.9%)	
1	58 (44.6%)	
2	18 (13.8%)	
3	4 (3.1%)	
4	2 (1.5%)	
Lesion 1 PIRADS		82
1	3 (3.7%)	
2	1 (1.2%)	
3	17 (20.7%)	
4	45 (54.9%)	
5	16 (19.5%)	
Lesion 2 PIRADS		23
3	8 (34.8%)	
4	11 (47.8%)	
5	4 (17.4%)	
Lesion 3 PIRADS		6
2	1 (16.7%)	
3	2 (33.3%)	
4	2 (33.3%)	
5	1 (16.7%)	
Lesion 4 PIRADS		2
3	1 (50.0%)	
4	1 (50.0%)	
Lesion 1 Likert		80
2	5 (6.3%)	
3	19 (23.8%)	
4	30 (37.5%)	
5	17 (21.3%)	
Unknown	9 (11.3%)	
Lesion 2 Likert		23

3	6 (26.1%)	
4	10 (43.5%)	
5	4 (17.4%)	
Unknown	3 (13.0%)	
Lesion 3 Likert		6
3	2 (33.3%)	
4	2 (33.3%)	
5	1 (16.7%)	
Unknown	1 (16.7%)	
Lesion 4 Likert		2
3	1 (50.0%)	
Unknown	1 (50.0%)	
Was a prostate biopsy performed?		132
No	58 (43.9%)	
Yes	74 (56.1%)	
What type of biopsy?		72
Targeted	39 (54.2%)	
Transperineal template +/- target	33 (45.8%)	
Was cancer found?		72
No	18 (25.0%)	
Yes	54 (75.0%)	
Gleason Grade		54
3+3	9 (16.7%)	
3+4	27 (50.0%)	
3+5	2 (3.7%)	
4+3	8 (14.8%)	
4+4	2 (3.7%)	
4+5	5 (9.3%)	
5+4	1 (1.9%)	
Maximum Cancer Core Length	7.4 (4.8)	51
MRI T Staging		82
rT2a	50 (61.0%)	
rT2b	1 (1.2%)	
rT2c	21 (25.6%)	
rT3a	7 (8.5%)	
rT3b	3 (3.7%)	
MRI N Staging N0 - No malignant nodes N1 - Malignant nodes inside the pelvis		82
N0	82 (100.0%)	
MRI M Staging M0 - No mets M1a - Malignant lymph nodes outside the pelvis M1b -		82
M0	82 (100.0%)	
Was staging imaging performed?		135
No	119 (88.1%)	

Yes	16 (11.9%)	
M stage M0 - No mets M1a - Non-regional lymph nodes M1b - Bone mets M1c - Visce		16
M0	16 (100.0%)	

Data are presented as N (%)

7.2 Visit 2

	N (%)	Records Available
Since the last visit has the participant been diagnosed with any new medical pro		130
No	124 (95.4%)	
Yes	6 (4.6%)	
Number of Lesions Identified on MRI		5
1	3 (60.0%)	
2	2 (40.0%)	
Lesion 1 PIRADS		5
3	1 (20.0%)	
4	4 (80.0%)	
Lesion 2 PIRADS		2
3	2 (100.0%)	
Lesion 1 LIKERT		5
4	2 (40.0%)	
Unknown	3 (60.0%)	
Lesion 2 LIKERT		2
3	1 (50.0%)	
Unknown	1 (50.0%)	
Biopsy?		8
No	7 (87.5%)	
Yes	1 (12.5%)	
What type of biopsy?		1
Targeted	1 (100.0%)	
Was cancer found?		1
Yes	1 (100.0%)	
Gleason Grade		1
4+3	1 (100.0%)	
Maximum Cancer Core Length	6.0 (.)	1
MRI T Staging		5
rT2a	4 (80.0%)	
rT2b	1 (20.0%)	
MRI N Staging N0 - No malignant nodes N1 - Malignant nodes inside the pelvis		5
N0	5 (100.0%)	
MRI M Staging M0 - No mets M1a - Malignant lymph nodes outside the pelvis M1b -		5
M0	5 (100.0%)	
Staging scans?		8
No	6 (75.0%)	
Yes	2 (25.0%)	
M stage M0 - No mets M1a - Non-regional lymph nodes M1b - Bone mets M1c - Visce		

M0	2 (100.0%)	
Since last meeting has the participant undergone treatment for prostate cancer?		131
No	84 (64.1%)	
Yes	47 (35.9%)	
What type?		47
Active surveillance	12 (25.5%)	
Radical Prostatectomy	8 (17.0%)	
External Beam Radiotherapy and Hormones	10 (21.3%)	
LDR Brachytherapy	2 (4.3%)	
Hormones	4 (8.5%)	
Focal therapy	11 (23.4%)	
Was this a salvage prostatectomy? I.e., after focal therapy		7
No	7 (100.0%)	
Was adjuvant radiotherapy given?		5
No	5 (100.0%)	

Data are presented as N (%)

8 Safety Reporting

There were 78 Adverse events in total of 39 patients

Table 8.1: Summary of Adverse events

	Total N=78
Severity	
Mild	27 (34.6%)
Moderate	48 (61.5%)
Severe	3 (3.8%)
Is this a serious adverse event? (SAE)	
No	75 (96.2%)
Yes	3 (3.8%)
Relationship to Study Treatment	
Unrelated	58 (74.4%)
Unlikely to be related	4 (5.1%)
Possibly related	6 (7.7%)
Probably related	10 (12.8%)
Action Taken with study intervention	
None	77 (98.7%)
Study Intervention Withdrawn	1 (1.3%)
Outcome	
Recovered / Resolved	31 (39.7%)
Recovering / Resolving	16 (20.5%)
Unresolved / Not Recovered / Persistent	30 (38.5%)
Unknown / Not assessable	1 (1.3%)

Table 8.2: Severity of the most severe AE of each patient

	Total N=39
Severity	
Mild	11 (28.2%)
Moderate	26 (66.7%)
Severe	2 (5.1%)

Table 8.3: Listing of all Adverse Events

Record ID	Reported Term for Adverse Event	Date of Onset	End Date	Severity	Relationship to Study Treatment	Action Taken with study intervention	Outcome
CXH-71	Abnormal gait	21/09/2021		Moderate	Unrelated	None	Unresolved / Not Recovered / Persistent
CXH-8	Anxiety	23/03/2021	25/03/2021	Moderate	Unrelated	None	Recovered / Resolved
CXH-13	Ataxia	15/04/2022	16/05/2022	Moderate	Unrelated	None	Recovered / Resolved
CXH-26	Back pain	06/05/2021		Moderate	Unrelated	None	Recovering / Resolving
CXH-60	Back pain	02/11/2021	09/11/2021	Moderate	Unrelated	None	Recovered / Resolved
465-25	COVID 19 infection	01/05/2022	01/06/2022	Mild	Unrelated	None	Recovered / Resolved
CXH-7	COVID 19 infection	01/09/2021	01/10/2021	Moderate	Unrelated	None	Recovered / Resolved
CXH-70	Catheter pain	22/11/2021		Mild	Unrelated	None	Unresolved / Not Recovered / Persistent
CXH-22	Cellulitis	13/08/2021	17/08/2021	Mild	Unrelated	None	Recovered / Resolved
465-40	Chest pain	14/01/2022		Moderate	Unrelated	None	Unresolved / Not Recovered / Persistent
CXH-17	Cognitive dysfunction	25/03/2021	14/12/2021	Moderate	Unrelated	None	Recovered / Resolved
CXH-7	Community acquired pneumonia	31/10/2021		Moderate	Unrelated	None	Recovered / Resolved
CXH-20	Constipation	22/04/2021	01/06/2021	Mild	Unrelated	None	Recovered / Resolved
CXH-9	Deep vein thrombosis	14/10/2021		Mild	Unrelated	None	Recovering / Resolving
CXH-17	Depression	25/03/2021	14/12/2021	Moderate	Unrelated	None	Recovering / Resolving
CXH-60	Diarrhoea and vomiting	01/08/2021	12/08/2021	Moderate	Unrelated	None	Recovered / Resolved
465-13	Erectile Dysfunction	06/01/2022		Moderate	Probably related	None	Unresolved / Not Recovered / Persistent

Record ID	Reported Term for Adverse Event	Date of Onset	End Date	Severity	Relationship to Study Treatment	Action Taken with study intervention	Outcome
CXH-20	Erectile Dysfunction	22/04/2021		Moderate	Unrelated	None	Unresolved / Not Recovered / Persistent
CXH-38	Erectile Dysfunction	01/04/2021		Moderate	Probably related	None	Unresolved / Not Recovered / Persistent
CXH-4	Erectile Dysfunction	10/11/2021		Moderate	Probably related	None	Unresolved / Not Recovered / Persistent
CXH-47	Erectile Dysfunction	14/09/2021		Mild	Probably related	None	Recovering / Resolving
CXH-73	Erectile Dysfunction	17/11/2021		Mild	Possibly related	None	Unresolved / Not Recovered / Persistent
CXH-25	Erectile dysfunction (worsening)	08/01/2021		Moderate	Unrelated	None	Unresolved / Not Recovered / Persistent
CXH-23	Faecal Frequency	13/04/2021		Moderate	Unrelated	None	Unresolved / Not Recovered / Persistent
CXH-23	Fatigue	13/04/2021		Moderate	Unrelated	None	Unresolved / Not Recovered / Persistent
CXH-73	Fatigue	17/11/2021		Mild	Possibly related	None	Unresolved / Not Recovered / Persistent
CXH-77	Fatigue	04/11/2021	02/12/2021	Moderate	Unrelated	None	Recovered / Resolved
CXH-16	Flare of ulcerative Colitis	01/01/2022		Moderate	Unrelated	None	Recovered / Resolved
CXH-11	Groin abscess	15/04/2022		Moderate	Unrelated	None	Recovered / Resolved
CXH-25	Haemospermia	08/01/2021		Mild	Unrelated	None	Recovering / Resolving
CXH-43	Haematuria	11/03/2021		Mild	Probably related	None	Recovered / Resolved
CXH-58	Haematuria	09/02/2022	09/02/2022	Mild	Unrelated	None	Recovered / Resolved
CXH-60	Head injury	20/09/2021	20/09/2021	Moderate	Unrelated	None	Recovered / Resolved
CXH-77	Headaches	04/11/2021	02/12/2021	Mild	Unrelated	None	Recovered / Resolved

Record ID	Reported Term for Adverse Event	Date of Onset	End Date	Severity	Relationship to Study Treatment	Action Taken with study intervention	Outcome
CXH-26	High post void residual volumes	18/10/2021		Moderate	Unrelated	None	Unresolved / Not Recovered / Persistent
CXH-60	Hip sprain	29/11/2021		Moderate	Unrelated	None	Recovering / Resolving
465-21	Hot flashes	01/02/2022		Mild	Possibly related	None	Unresolved / Not Recovered / Persistent
CXH-38	Hot flashes	21/10/2020		Moderate	Unrelated	None	Unresolved / Not Recovered / Persistent
CXH-73	Hot flashes	18/08/2021		Moderate	Possibly related	Study Intervention Withdrawn	Recovering / Resolving
CXH-22	Inguinal Hernia repair	19/06/2021	19/06/2021	Mild	Unrelated	None	Recovered / Resolved
465-40	Intermittent Confusion	14/01/2022		Moderate	Unrelated	None	Unresolved / Not Recovered / Persistent
CXH-77	Knee pain	21/10/2021		Moderate	Unrelated	None	Recovering / Resolving
CXH-13	Left Ring Finger fracture	25/10/2021		Severe	Unrelated	None	Recovered / Resolved
CXH-60	Leg pain	30/12/2021	30/12/2021	Moderate	Unrelated	None	Recovered / Resolved
CXH-5	Loss of balance	01/07/2020		Moderate	Unrelated	None	Unresolved / Not Recovered / Persistent
465-1	Low urinary flow rate	16/12/2021		Mild	Probably related	None	Recovering / Resolving
465-21	Lower urinary tract symptoms	01/02/2022		Mild	Unlikely to be related	None	Unresolved / Not Recovered / Persistent
CXH-1	Lower urinary tract symptoms	10/06/2021		Mild	Unrelated	None	Unresolved / Not Recovered / Persistent
CXH-10	Lower urinary tract symptoms	12/03/2021		Moderate	Possibly related	None	Recovering / Resolving
CXH-11	Lower urinary tract symptoms	10/02/2022		Moderate	Unlikely to be related	None	Recovering / Resolving
CXH-41	Lower urinary tract symptoms	30/09/2021	29/12/2021	Mild	Probably related	None	Recovered / Resolved

Record ID	Reported Term for Adverse Event	Date of Onset	End Date	Severity	Relationship to Study Treatment	Action Taken with study intervention	Outcome
CXH-5	Lower urinary tract symptoms	01/05/2021		Mild	Unlikely to be related	None	Unresolved / Not Recovered / Persistent
CXH-23	Nocturia	13/04/2021		Mild	Unrelated	None	Unresolved / Not Recovered / Persistent
CXH-73	Nocturia	17/11/2021		Moderate	Possibly related	None	Unresolved / Not Recovered / Persistent
CXH-43	Perineal pain	11/05/2021	14/05/2021	Mild	Probably related	None	Recovered / Resolved
CXH-23	Poor urinary flow	13/04/2021		Mild	Unrelated	None	Unresolved / Not Recovered / Persistent
CXH-23	Post traumatic epilepsy	13/03/2021	13/03/2021	Severe	Unrelated	None	Recovered / Resolved
CXH-17	Post traumatic stress disorder	25/03/2021	14/12/2021	Mild	Unrelated	None	Recovered / Resolved
CXH-24	Prostatitis	08/09/2021		Mild	Unrelated	None	Recovering / Resolving
CXH-13	Psychosis	25/10/2021		Severe	Unrelated	None	Unresolved / Not Recovered / Persistent
CXH-28	Pyelonephritis	08/02/2021		Moderate	Unrelated	None	Unknown / Not assessable
CXH-22	Recurrent Urinary Tract Infections	17/02/2021	11/10/2021	Moderate	Unrelated	None	Recovered / Resolved
CXH-6	Recurrent urinary tract infections	01/06/2021	19/10/2021	Moderate	Unrelated	None	Recovered / Resolved
CXH-16	Reduced ejaculatory volume	23/11/2020		Mild	Unrelated	None	Unresolved / Not Recovered / Persistent
CXH-24	Retinal detachment	07/12/2021		Moderate	Unrelated	None	Recovered / Resolved
CXH-13	Right groin pain	15/04/2022	16/05/2022	Moderate	Unrelated	None	Recovered / Resolved
CXH-38	Sprained ankle	05/08/2021	29/11/2021	Moderate	Unrelated	None	Recovered / Resolved
465-13	Stress Urinary Incontinence	06/01/2022		Moderate	Probably related	None	Unresolved / Not Recovered / Persistent

Record ID	Reported Term for Adverse Event	Date of Onset	End Date	Severity	Relationship to Study Treatment	Action Taken with study intervention	Outcome
CXH-57	Total hip arthroplasty	20/12/2021	22/12/2021	Moderate	Unrelated	None	Recovered / Resolved
CXH-14	Transient Ischaemic Attack	10/01/2021	10/01/2021	Moderate	Unrelated	None	Recovered / Resolved
CXH-42	Tremor	01/03/2021		Moderate	Unrelated	None	Unresolved / Not Recovered / Persistent
CXH-44	Upper respiratory tract infection	22/09/2021		Mild	Unrelated	None	Recovering / Resolving
CXH-20	Urinary incontinence	22/04/2021	10/06/2021	Mild	Unrelated	None	Recovering / Resolving
CXH-42	Urinary incontinence	18/11/2021		Moderate	Probably related	None	Recovering / Resolving
CXH-5	Watery stool	01/06/2021		Moderate	Unlikely to be related	None	Unresolved / Not Recovered / Persistent
CXH-38	Weight gain	03/06/2021		Moderate	Unrelated	None	Unresolved / Not Recovered / Persistent
465-3	Worsening shortness of breath	25/02/2022		Moderate	Unrelated	None	Unresolved / Not Recovered / Persistent
CXH-23	calf swelling	17/10/2021		Moderate	Unrelated	None	Recovering / Resolving

Table 8.4: Listing of all Serious Adverse Events

Record ID	Reported Term for Adverse Event	Is this a serious adverse event? (SAE)	Relationship to Study Treatment	SAE term	Date of SAE onset (if different from start date of associated AE)	Where did the SAE take place?	Why was the event serious?	Severity
CXH-11	Groin abscess	Yes	Unrelated	Incision and drainage, hospital admission	15/04/2022	Hospital	Required inpatient hospitalisation or prolongation of existing hospitalisation	Moderate
CXH-13	Left Ring Finger fracture	Yes	Unrelated	Left Ring Finger fracture	25/10/2021	Home	Required inpatient hospitalisation or prolongation of existing hospitalisation	Severe
CXH-13	Psychosis	Yes	Unrelated	Psychosis	25/10/2021	Home	Required inpatient hospitalisation or prolongation of existing hospitalisation	Severe

9 Protocol Deviations

There were 19 protocol deviations recorded in total.

Table 9.1: List of all protocol deviations

Record ID	Is this a serious breach?	Description of Deviation / Violation	Deviation Category / Code	Date Deviation Occurred	Date ICTU Notified (if applicable):	Study manager comments	PI / CI comments
461-1	No	Patient did not complete PROMS despite reminders	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	30/11/2021			
461-3	No	Participant did not complete PROMS despite reminders	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	06/11/2021			
465-13	No	Participant did not complete and return PROMS despite several reminders	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	18/10/2021			
465-31	No	Patient did not complete PROMS regarding sexual function	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	07/12/2021			

465-37	No	Patient did not completed some PROMS fields despite multiple reminders	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	31/01/2022			
465-39	No	Patient did not complete PROMS despite reminders	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	31/01/2022			
465-4	No	Patient did not complete PROMS questionnaires despite reminders	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	29/09/2021			
465-8	No	Patient did not complete PROMS despite multiple reminders	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	30/09/2021			
CXH-19	No	Participant did not complete PROMS despite reminders	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	23/12/2020			
CXH-22	No	Participant did not complete PROMS despite reminders	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	15/01/2021			

CXH-23	No	Participant did not complete PROMS despite reminders	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	15/01/2021			
CXH-23	No	Participant did not complete PROMS despite reminders	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	20/07/2021			
CXH-23	No	Participant did not complete PROMS despite reminders	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	04/06/2021			
CXH-25	No	Participant did not complete PROMS despite reminders	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	29/07/2021			
CXH-25	No	Participant did not complete PROMS despite reminders	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	02/02/2022			
CXH-25	No	Participant did not complete PROMS despite reminders	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	03/02/2021			

CXH-26	No	Participant did not complete PROMS despite reminders	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	04/06/2021			
CXH-7	No	PROMS questionnaires not completed by participant. Repeated reminders sent to no avail.	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	23/10/2021			
CXH-8	No	PROMS questions related to sexual function not answered as participant has no partner	Study measurements/assessments - Primary outcome measure/ Secondary outcome measure/ Safety outcome	28/10/2021			

10Appendix

Medical history terms (as recorded in RedCap)

	Total N=214
Medical History Term	
Abdominal wall lipoma	1 (0.5%)
Adenocarcinoma of the prostate	1 (0.5%)
Anxiety	1 (0.5%)
Appendicectomy	1 (0.5%)
Appendicitis	1 (0.5%)
Asthma	8 (3.7%)
Atrial fibrillation	2 (0.9%)
BCC	1 (0.5%)
Barrett's Oesophagus	1 (0.5%)
Basal Cell Carcinoma	1 (0.5%)
Basal cell carcinoma	1 (0.5%)
Benign Prostatic Hypertrophy	1 (0.5%)
Benign prostatic enlargement	1 (0.5%)
Bladder outlet obstruction	1 (0.5%)
Bladder outlet obstruction / BPH	1 (0.5%)
CABG 2003	1 (0.5%)
COPD	1 (0.5%)
Cataracts	3 (1.4%)
Cervical spondylolithiasis	1 (0.5%)
Cholecystectomy	1 (0.5%)
Chronic kidney disease	1 (0.5%)
Chronic obstructive pulmonary disease	3 (1.4%)
Colon cancer	1 (0.5%)
DVT in right upper limb	1 (0.5%)
Deafness	1 (0.5%)
Depression	2 (0.9%)
Depression in 2014	1 (0.5%)
Diabetes	1 (0.5%)
Diabetic	1 (0.5%)
Diverticular disease	1 (0.5%)
Dupuytren's contracture	1 (0.5%)
Dupuytren's contracture of the hand	1 (0.5%)
Epilepsy	1 (0.5%)
Erectile dysfunction	5 (2.3%)
Follicular lymphoma	1 (0.5%)
Fracture of distal radius and scaphoid-lunate dislocation	1 (0.5%)
Gastro-oesophageal reflux disease	2 (0.9%)
Gout	4 (1.9%)
HIV	1 (0.5%)
Haemorrhoids	1 (0.5%)
Hiatus hernia	2 (0.9%)
High Blood pressure	1 (0.5%)
High Cholesterol	2 (0.9%)
Hodgkin Lymphoma	1 (0.5%)
Hypercholesterolaemia	1 (0.5%)
Hypercholesterolaemia	9 (4.2%)
Hyperlipidaemia	2 (0.9%)

Hypertension	25 (11.7%)
Hypertension	1 (0.5%)
Hypothyroidism	1 (0.5%)
IgA nephropathy	1 (0.5%)
Incisional hernia	1 (0.5%)
Inflammatory bowel disease	1 (0.5%)
Inguinal hernia	2 (0.9%)
Ischaemic heart disease	1 (0.5%)
LUTS	1 (0.5%)
Left inguinal hernia	1 (0.5%)
Left nephrectomy for RCC	1 (0.5%)
Left ventricular hypertrophy	1 (0.5%)
Lentigo maligna	1 (0.5%)
Lower urinary tract symptoms	6 (2.8%)
Lumbar spinal stenosis	1 (0.5%)
MI in 2014; coronary heart disease	1 (0.5%)
MI in 2019, had two coronary stents	1 (0.5%)
Melanoma in left Thigh & others 1990	1 (0.5%)
Mitral valve repair	1 (0.5%)
Non diabetic hyperglycaemia	1 (0.5%)
Non-arteritic anterior ischaemic optic neuropathy	1 (0.5%)
Non-insulin dependent diabetes mellitus	2 (0.9%)
Obesity	1 (0.5%)
Obstructive sleep apnea	2 (0.9%)
Osteoarthritis	8 (3.7%)
Osteoporosis	1 (0.5%)
Paroxysmal Atrial Fibrillation	1 (0.5%)
Peyronie's disease	1 (0.5%)
Polymyalgia rheumatica	1 (0.5%)
Posterior vitreous detachment	1 (0.5%)
Prostate Cancer	1 (0.5%)
Prostatic Adenocarcinoma	1 (0.5%)
Prostatitis	1 (0.5%)
Psoriasis	1 (0.5%)
Raised blood urate	1 (0.5%)
Reactive airways disease	1 (0.5%)
Reflux	1 (0.5%)
Renal calculi	1 (0.5%)
Renal stones	1 (0.5%)
Right inguinal hernia	1 (0.5%)
SCC neck mets	1 (0.5%)
Schizophrenia	1 (0.5%)
Seborrhoeic keratosis	1 (0.5%)
Sensorineural hearing loss	1 (0.5%)
Stent 2018	1 (0.5%)
Stroke	1 (0.5%)
T2 Diabetes	1 (0.5%)
TIA	1 (0.5%)
Temporal lobe epilepsy	1 (0.5%)
Testicular cancer	1 (0.5%)
Transient Ischaemic attack	1 (0.5%)
Type 1 diabetes	1 (0.5%)
Type 2 diabetes	1 (0.5%)
Type II diabetes	1 (0.5%)
Varicocele	1 (0.5%)
Varicose veins	1 (0.5%)
anxiety	1 (0.5%)

brain meningitis in 2012	1 (0.5%)
chronic kidney disease	1 (0.5%)
depression	1 (0.5%)
diabetic	1 (0.5%)
emphysema	1 (0.5%)
had 2MI in the past- both are silent MI, had CABG	1 (0.5%)
high blood pressure	10 (4.7%)
high cholesterol	8 (3.7%)
high cholesterol	2 (0.9%)
high pressure in the eyes	1 (0.5%)
hypothyroidism	1 (0.5%)
inflammatory bowel disease	1 (0.5%)
kidney stones	1 (0.5%)
left Orchiectomy due to infection 2009	1 (0.5%)
left leg DVT in 2018	1 (0.5%)
left patella fracture Dec 2020	1 (0.5%)
low HB	1 (0.5%)
memory issue as started when had a fall and head injury 6 years ago	1 (0.5%)
on Levothyroxine	1 (0.5%)
polyps removed from rectum & caecum in July 2021	1 (0.5%)
radical laparoscopic nephrectomy March 2019	1 (0.5%)
seborrheic dermatitis	1 (0.5%)
