Table 6.1
Summary of Patient Disposition

	Duodart (N=59)
Number of Enrolled Patients (ITT population)	59 (100%)
Completion Status	
Completed 6 Months of Treatment	52 (88%)
Prematurely Withdrawn Prior to Visit 5 (Month 6) [1]	7 (12%)
Primary Reason for Premature Withdrawal [1]	
Adverse Event	3 (5%)
Lost to Follow-up	1 (2%)
Withdrawal by Subject	3 (5%)
Protocol Deviation	0
Study Closed/Terminated	0
Investigator Discretion	0

[1] Premature withdrawal prior to Visit 5 (Month 6) is defined as failure to complete the 6 month treatment period.

Table 6.2
Summary of Patient Discontinuation, by Visit

	Duodart (N=59)
Visit 1 (Month 1)	
Discontinued Screening - Visit 1 (Month 1)	3 (5%)
Completed Through Visit 1 (Month 1)	56 (95%)
Visit 2 (Month 2)	
Discontinued Visit 1 (Month 1) - Visit 2 (Month 2)	1 (2%)
Completed Through Visit 2 (Month 2)	55 (93%)
Visit 3 (Month 3)	
Discontinued Visit 2 (Month 2) - Visit 3 (Month 3)	1 (2%)
Completed Through Visit 3 (Month 3)	54 (92%)
Visit 4 (Month 4.5)	
Discontinued Visit 3 (Month 3) - Visit 4 (Month 4.5)	2 (3%)
Completed Through Visit 4 (Month 4.5)	52 (88%)
Visit 5 (Month 6)	
Discontinued Visit 4 (Month 4.5) - Visit 5 (Month 6)	0
Completed Through Visit 5 (Month 6)	52 (88%)

Table 6.3
Summary of Inclusion/Exclusion Criteria Deviations

	Duodart (N=59)
Any Deviations Criteria	5 (8%)
Inclusion	
Maximum flow rate (Qmax) >5 mL/s and <=15 mL/s and post-void residual volume of <150 mL at screening.	1 (2%)
Prostate volume >=30 mL (determined by transrectal ultrasonography).	2 (3%)
Exclusion	
History of hepatic impairment or abnormal liver function tests at screening (defined ALT, AST, and/or alkaline phosphatase >2 times the UL of normal, or total bilirubin >1.5 times the UL of normal).	1 (2%)
History of renal insufficiency, or serum creatinine >1.5 times the upper limit of normal at screening.	1 (2%)

Table 6.4
Summary of Demographic and Baseline Characteristics

		Duodart (N=59)
Age (Years)	n	59
	Mean	66.8
	SD	8.38
	Median	65.0
	Min.	53
	Max.	89
Age Category	n	59
	<65 Years	27(46%)
	>=65 Years	32(54%)
Sex	Male	59(100%)
	Female	0
Race	Asian	59(100%)
Height (cm)	n	59
	Mean	164.7
	SD	5.47
	Median	165.0
	Min.	150
	Max.	175

Table 6.4
Summary of Demographic and Baseline Characteristics

		Duodart (N=59)
Weight (kg)	n	59
	Mean	61.7
	SD	8.76
	Median	61.0
	Min.	44
	Max.	80

Table 6.5
Summary of Concomitant Medications

ATC Level 1 Ingredient	Duodart (N=59)
Any Medication	25 (42%)
Cardiovascular System	
Any Medication	13 (22%)
Amlodipine	8 (14%)
Trimetazidine	3 (5%)
Enalapril	2 (3%)
Ginkgo Biloba	2 (3%)
Multiple Ingredient	2 (3%)
Atorvastatin Calcium	1 (2%)
Bisoprolol	1 (2%)
Daflon Nos	1 (2%)
Felodipine	1 (2%)
Furosemide	1 (2%)
Glyceryl Trinitrate	1 (2%)
Perindopril	1 (2%)
Rosuvastatin	1 (2%)
Simvastatin	1 (2%)
Alimentary Tract and Metabolism	
Any Medication	7 (12%)
Gliclazide	2 (3%)
Acetylsalicylic Acid	1 (2%)
Calcium Glucoheptonate	1 (2%)
Metformin Hydrochloride	1 (2%)

Note: Medications were coded using the GSK Drug Anatomical Therapeutic Chemical Dictionary.

Table 6.5
Summary of Concomitant Medications

ATC Level 1 Ingredient	Duodart (N=59)
Alimentary Tract and Metabolism (Continued)	
Multiple Ingredient	1 (2%)
Pantoprazole Sodium	1 (2%)
Rebamipide	1 (2%)
Various	
Any Medication	7 (12%)
Medication Unknown	3 (5%)
Multiple Ingredient	3 (5%)
Ginkgo Biloba	2 (3%)
Musculo-Skeletal System	
Any Medication	5 (8%)
Glucosamine	2 (3%)
Acetylsalicylic Acid	1 (2%)
Etoricoxib	1 (2%)
Methocarbamol	1 (2%)
Multiple Ingredient	1 (2%)
Blood and Blood forming Organs	
Any Medication	4 (7%)
Chymotrypsin	2 (3%)
Acetylsalicylic Acid	1 (2%)
Intravenous Fluid (Nos)	1 (2%)
Nervous System	
Any Medication	4 (7%)

Note: Medications were coded using the GSK Drug Anatomical Therapeutic Chemical Dictionary.

Table 6.5
Summary of Concomitant Medications

ATC Level 1 Ingredient	Duodart (N=59)
Nervous System (Continued)	
Ginkgo Biloba	2 (3%)
Acetylsalicylic Acid	1 (2%)
Multiple Ingredient	1 (2%)
Antiinfectives for Systemic Use	
Any Medication	3 (5%)
Clarithromycin	2 (3%)
Chloramphenicol	1 (2%)
Tobramycin	1 (2%)
Dermatologicals	
Any Medication	2 (3%)
Chloramphenicol	1 (2%)
Glyceryl Trinitrate	1 (2%)
Respiratory System	
Any Medication	2 (3%)
Multiple Ingredient	1 (2%)
Salbutamol	1 (2%)
Sensory Organs	
Any Medication	2 (3%)
Chymotrypsin	2 (3%)
Chloramphenicol	1 (2%)
Tobramycin	1 (2%)

Note: Medications were coded using the GSK Drug Anatomical Therapeutic Chemical Dictionary.

Table 6.5
Summary of Concomitant Medications

ATC Level 1 Ingredient	Duodart (N=59)
Genito Urinary System and Sex Hormones	
Any Medication	1 (2%)
Chloramphenicol	1 (2%)

Note: Medications were coded using the GSK Drug Anatomical Therapeutic Chemical Dictionary.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_6_5.sas 27MAY2015 04:57

Table 6.6
Summary of Compliance to Study Treatment

		Duodart (N=59)
Overall Compliance (%)	n	58
	Mean	99.0
	SD	3.00
	Median	99.0
	Min.	77
	Max.	101
	<75%	0
	75-125%	58 (98%)
	>125%	0
	Missing	1 (2%)

Overall compliance (%) = 100* (number of capsules consumed during the study)/ (number of days that the patient was on treatment)

Table 6.7
Summary of Exposure to Study Treatment

		Duodart (N=59)
Exposure to Study Treatment (Days) [1]	n	58
	Mean	164.4
	SD	39.69
	Median	177.0
	Min.	13
	Max.	183
	1 - 30	3 (5%)
	31 - 60	1 (2%)
	61 - 90	1 (2%)
	91 - 135	1 (2%)
	>135	52 (88%)
	Missing	1 (2%)

[1] Study Treatment Exposure (Days) = Treatment Stop Date - Treatment Start Date + 1, excluding dose interruptions.

Table 7.1
Summary of IPSS Imputations

	Duodart (N=59)
Number of patients with an least one administered questionnaire	59
Number (%) of patients with at least one imputation	0
Number of questionnaires (across patients and visits)	111
Number (%) of questionnaires not requiring an imputation [1]	111 (100%)
Number (%) of questionnaires in which an imputation was performed [2]	0
Among questionnaires with an imputation, number missing	
1 question	0
2 questions	0
3 questions	0
Number (%) of questionnaires in which an imputation could not be performed [3]	0
Among questionnaires with no imputation, number missing	
4 questions	0
5 questions	0
6 questions	0

[1] All 7 questions answered.
[2] 1-3 responses missing.
[3] 4-6 responses missing.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_7_1.sas 27MAY2015 04:57

Table 7.2
Summary of IPSS At Baseline

	Duodart (N=59)
n	59
Mean	19.2
SD	4.28
Median	19.0
Min.	13
Max.	28

Note: Baseline is defined as the value obtained at Screening.

Table 7.3
Summary of IPSS At Post-Baseline Visit (At Visit)

IPSS At:	Duodart (N=59)
Visit 5 (Month 6)	
n	52
Mean	10.8
SD	4.35
Median	10.0
Min.	3
Max.	26

Table 7.4
Summary of IPSS Change from Baseline (At Visit)

IPSS Change from Baseline At:	Duodart (N=59)
Visit 5 (Month 6)	
n	52
Mean	-8.3
SD	3.92
Median	-8.0
Min.	-17
Max.	0
95% Confidence Interval [1]	-9.34, -7.16
p-value [1]	<0.001

[1] 95% CI and p-value are based on t-test for the change from baseline in IPSS at Visit 5.

Table 7.5
Summary of IPSS Percent Change from Baseline (At Visit)

IPSS Percent Change from Baseline At:	Duodart (N=59)
Visit 5 (Month 6)	
n	52
Mean	-43.5
SD	18.31
Median	-44.1
Min.	-80
Max.	0

Note: Percent change from baseline = 100*(post-baseline - baseline value)/baseline value.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_7_5.sas 27MAY2015 04:57

Table 7.6
Summary of Qmax (mL/s) At Baseline

	Duodart (N=59)
n	59
Mean	9.74
SD	2.900
Median	9.80
Min.	5.0
Max.	15.0

Note: Baseline is defined as the value obtained at Screening.

Table 7.7
Summary of Qmax (mL/s) At Each Post-Baseline Visit (LOCF)

Qmax At:	Duodart (N=59)
Visit 3 (Month 3)	
n	54
Mean	12.51
SD	5.140
Median	11.45
Min.	5.0
Max.	28.3
Visit 5 (Month 6)	
n	54
Mean	11.66
SD	4.278
Median	11.45
Min.	0.7
Max.	20.3

Table 7.8
Summary of Qmax (mL/s) At Each Post-Baseline Visit (At Visit)

Qmax At:	Duodart (N=59)
Visit 3 (Month 3)	
n	54
Mean	12.51
SD	5.140
Median	11.45
Min.	5.0
Max.	28.3
Visit 5 (Month 6)	
n	52
Mean	11.69
SD	4.356
Median	11.75
Min.	0.7
Max.	20.3

Table 7.9
Summary of Qmax (mL/s) Change from Baseline (LOCF)

Qmax Change from Baseline At:	Duodart (N=59)
Visit 3 (Month 3)	
n	54
Mean	2.77
SD	4.361
Median	2.40
Min.	-6.8
Max.	18.4
95% Confidence Interval [1]	1.58, 3.96
p-value [1]	<0.001
Visit 5 (Month 6)	
n	54
Mean	1.92
SD	3.651
Median	2.30
Min.	-5.1
Max.	9.0
95% Confidence Interval [1]	0.92, 2.92
p-value [1]	<0.001

[1] 95% CI and p-values are based on t-test for the change from baseline in Qmax at each post-baseline.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_7_9.sas 27MAY2015 04:57

Table 7.10
Summary of Qmax (mL/s) Change from Baseline (At Visit)

Qmax Change from Baseline At:	Duodart (N=59)
Visit 3 (Month 3)	
n	54
Mean	2.77
SD	4.361
Median	2.40
Min.	-6.8
Max.	18.4
95% Confidence Interval [1]	1.58, 3.96
p-value [1]	<0.001
Visit 5 (Month 6)	
n	52
Mean	2.01
SD	3.684
Median	2.50
Min.	-5.1
Max.	9.0
95% Confidence Interval [1]	0.98, 3.03
p-value [1]	<0.001

[1] 95% CI and p-values are based on t-test for the change from baseline in Qmax at each post-baseline.

Table 7.11
Summary of Qmax Percent Change from Baseline (LOCF)

Qmax Percent Change from Baseline At:	Duodart (N=59)
Visit 3 (Month 3)	
n	54
Mean	31.22
SD	45.165
Median	26.11
Min.	-45.3
Max.	185.9
Visit 5 (Month 6)	
n	54
Mean	22.74
SD	43.038
Median	23.16
Min.	-86.0
Max.	121.6

Note: Percent change from baseline = 100*(post-baseline - baseline value)/baseline value.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_7_11.sas 27MAY2015 04:57

Table 7.12
Summary of Qmax Percent Change from Baseline (At Visit)

Qmax Percent Change from Baseline At:	Duodart (N=59)
Visit 3 (Month 3)	
n	54
Mean	31.22
SD	45.165
Median	26.11
Min.	-45.3
Max.	185.9
Visit 5 (Month 6)	
n	52
Mean	23.70
SD	43.516
Median	28.37
Min.	-86.0
Max.	121.6

Note: Percent change from baseline = 100*(post-baseline - baseline value)/baseline value.

Table 8.1
Summary of Adverse Events Starting On-Treatment, by Type

	Duodart (N=59)		
	#AE	#Sub (%)	95% Confidence Interval
Any Adverse Event	19	13 (22%)	12.3 - 34.7
Any Treatment Related Adverse Event	8	3 (5%)	1.1 - 14.1
Any Serious Adverse Event	1	1 (2%)	0.0 - 9.1
Any Adverse Event Leading to Study Treatment Discontinuation	2	2 (3%)	0.4 - 11.7
Any Adverse Event Leading to Withdrawal from the Study	2	2 (3%)	0.4 - 11.7
Any Fatal Adverse Event	0	0	0 - 6.1

Note: Includes adverse events with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
95% CI is calculated by using exact (Clopper-Pearson) method.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_1.sas 27MAY2015 04:57

Table 8.2
Summary of Adverse Events Starting Post-Treatment, by Type

	Duodart (N=59)	
	#AE	#Sub (%)
Any Adverse Event	2	2 (3%)
Any Treatment Related Adverse Event	1	1 (2%)
Any Serious Adverse Event	1	1 (2%)
Any Adverse Event Leading to Study Treatment Discontinuation	1	1 (2%)
Any Adverse Event Leading to Withdrawal from the Study	1	1 (2%)
Any Fatal Adverse Event	0	0

Note: Includes adverse events with onset after the treatment stop date.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_2.sas 27MAY2015 04:57

Table 8.3
Summary of Adverse Events Starting On-Treatment

Primary System Organ Class/ Preferred Term	Duodart (N=59) #AE	#Sub	(%)	95% Confidence Interval
Any Adverse Event	19	13	(22%)	12.3 - 34.7
General Disorders and Administration Site Conditions	4	3	(5%)	1.1 - 14.1
Fatigue	3	2	(3%)	0.4 - 11.7
Peripheral Swelling	1	1	(2%)	0.0 - 9.1
Nervous System Disorders	5	3	(5%)	1.1 - 14.1
Dizziness	4	2	(3%)	0.4 - 11.7
Headache	1	1	(2%)	0.0 - 9.1
Infections and Infestations	3	3	(5%)	1.1 - 14.1
Bronchitis	1	1	(2%)	0.0 - 9.1
Conjunctivitis	1	1	(2%)	0.0 - 9.1
Pharyngitis	1	1	(2%)	0.0 - 9.1
Investigations	2	2	(3%)	0.4 - 11.7
Alanine Aminotransferase Increased	1	1	(2%)	0.0 - 9.1
Hepatic Enzyme Increased	1	1	(2%)	0.0 - 9.1

Note: Includes adverse events with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
Note: Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term.
95% CI is calculated by using exact (Clopper-Pearson) method.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_3.sas 27MAY2015 04:57

Table 8.3
Summary of Adverse Events Starting On-Treatment

Primary System Organ Class/ Preferred Term	Duodart (N=59) #AE	#Sub	(%)	95% Confidence Interval
Renal and Urinary Disorders	1	1	(2%)	0.0 - 9.1
Dysuria	1	1	(2%)	0.0 - 9.1
Reproductive System and Breast Disorders	1	1	(2%)	0.0 - 9.1
Ejaculation Disorder	1	1	(2%)	0.0 - 9.1
Respiratory, Thoracic and Mediastinal Disorders	1	1	(2%)	0.0 - 9.1
Nasal Congestion	1	1	(2%)	0.0 - 9.1
Skin and Subcutaneous Tissue Disorders	1	1	(2%)	0.0 - 9.1
Pruritus	1	1	(2%)	0.0 - 9.1
Vascular Disorders	1	1	(2%)	0.0 - 9.1
Hypotension	1	1	(2%)	0.0 - 9.1

Note: Includes adverse events with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
Note: Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term.
95% CI is calculated by using exact (Clopper-Pearson) method.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_3.sas 27MAY2015 04:57

Table 8.4
Summary of Adverse Events Starting Post-Treatment

Primary System Organ Class/ Preferred Term	Duodart (N=59) #AE	#Sub (%)
Any Adverse Event	2	2 (3%)
Renal and Urinary Disorders	1	1 (2%)
Renal Colic	1	1 (2%)
Vascular Disorders	1	1 (2%)
Hypotension	1	1 (2%)

Note: Includes adverse events with onset after the treatment stop date.
Note: Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_4.sas 27MAY2015 04:57

Table 8.5
Summary of Adverse Events With Onset After the First Dose of Study Treatment

Primary System Organ Class/ Preferred Term	Duodart (N=59) #AE	#Sub (%)
Any Adverse Event	21	14 (24%)
General Disorders and Administration Site Conditions	4	3 (5%)
Fatigue	3	2 (3%)
Peripheral Swelling	1	1 (2%)
Nervous System Disorders	5	3 (5%)
Dizziness	4	2 (3%)
Headache	1	1 (2%)
Infections and Infestations	3	3 (5%)
Bronchitis	1	1 (2%)
Conjunctivitis	1	1 (2%)
Pharyngitis	1	1 (2%)
Investigations	2	2 (3%)
Alanine Aminotransferase Increased	1	1 (2%)
Hepatic Enzyme Increased	1	1 (2%)

Note: Includes adverse events with onset on or after the first dose of study treatment.
Note: Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_5.sas 27MAY2015 04:57

Table 8.5
Summary of Adverse Events With Onset After the First Dose of Study Treatment

Primary System Organ Class/ Preferred Term	Duodart (N=59) #AE	#Sub	(%)
Renal and Urinary Disorders	2	2	(3%)
Dysuria	1	1	(2%)
Renal Colic	1	1	(2%)
Reproductive System and Breast Disorders	1	1	(2%)
Ejaculation Disorder	1	1	(2%)
Respiratory, Thoracic and Mediastinal Disorders	1	1	(2%)
Nasal Congestion	1	1	(2%)
Skin and Subcutaneous Tissue Disorders	1	1	(2%)
Pruritus	1	1	(2%)
Vascular Disorders	2	1	(2%)
Hypotension	2	1	(2%)

Note: Includes adverse events with onset on or after the first dose of study treatment.
Note: Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_5.sas 27MAY2015 04:57

Table 8.6
Summary of Adverse Events Starting On-Treatment, Age Group

Primary System Organ Class/ Preferred Term	Age <65 Years: Duodart (N=27) #AE	Age <65 Years: Duodart (N=27) #Sub (%)	Age >=65 Years: Duodart (N=32) #AE	Age >=65 Years: Duodart (N=32) #Sub (%)	Total #AE	Total #Sub (%)
Any Adverse Event	9	6 (22%)	10	7 (22%)	19	13 (22%)
General Disorders and Administration Site Conditions	2	1 (4%)	2	2 (6%)	4	3 (5%)
Fatigue	2	1 (4%)	1	1 (3%)	3	2 (3%)
Peripheral Swelling	0	0	1	1 (3%)	1	1 (2%)
Nervous System Disorders	1	1 (4%)	4	2 (6%)	5	3 (5%)
Dizziness	0	0	4	2 (6%)	4	2 (3%)
Headache	1	1 (4%)	0	0	1	1 (2%)
Infections and Infestations	1	1 (4%)	2	2 (6%)	3	3 (5%)
Bronchitis	0	0	1	1 (3%)	1	1 (2%)
Conjunctivitis	1	1 (4%)	0	0	1	1 (2%)
Pharyngitis	0	0	1	1 (3%)	1	1 (2%)
Investigations	1	1 (4%)	1	1 (3%)	2	2 (3%)
Alanine Aminotransferase Increased	1	1 (4%)	0	0	1	1 (2%)
Hepatic Enzyme Increased	0	0	1	1 (3%)	1	1 (2%)

Note: Includes adverse events with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
Note: Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term w.r.t. Total.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_6.sas 27MAY2015 04:58

Table 8.6
Summary of Adverse Events Starting On-Treatment, Age Group

Primary System Organ Class/ Preferred Term	Age <65 Years Duodart (N=27) #AE	#Sub (%)	Age >=65 Years Duodart (N=32) #AE	#Sub (%)	Total #AE	#Sub (%)
Renal and Urinary Disorders	1	1 (4%)	0	0	1	1 (2%)
Dysuria	1	1 (4%)	0	0	1	1 (2%)
Reproductive System and Breast Disorders	1	1 (4%)	0	0	1	1 (2%)
Ejaculation Disorder	1	1 (4%)	0	0	1	1 (2%)
Respiratory, Thoracic and Mediastinal Disorders	1	1 (4%)	0	0	1	1 (2%)
Nasal Congestion	1	1 (4%)	0	0	1	1 (2%)
Skin and Subcutaneous Tissue Disorders	1	1 (4%)	0	0	1	1 (2%)
Pruritus	1	1 (4%)	0	0	1	1 (2%)
Vascular Disorders	0	0	1	1 (3%)	1	1 (2%)
Hypotension	0	0	1	1 (3%)	1	1 (2%)

Note: Includes adverse events with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
Note: Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term w.r.t. Total.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_6.sas 27MAY2015 04:58

Table 8.7
Summary of Adverse Events Starting On-Treatment, by Maximum Intensity

Primary System Organ Class/ Preferred Term	Duodart (N=59) Mild	Moderate	Severe
Any Adverse Event [1]	8 (14%)	4 (7%)	1 (2%)
General Disorders and Administration Site Conditions	1 (2%)	2 (3%)	0
Fatigue	0	2 (3%)	0
Peripheral Swelling	1 (2%)	0	0
Infections and Infestations	3 (5%)	0	0
Bronchitis	1 (2%)	0	0
Conjunctivitis	1 (2%)	0	0
Pharyngitis	1 (2%)	0	0
Investigations	1 (2%)	0	1 (2%)
Alanine Aminotransferase Increased	1 (2%)	0	0
Hepatic Enzyme Increased	0	0	1 (2%)
Nervous System Disorders	2 (3%)	1 (2%)	0
Dizziness	1 (2%)	1 (2%)	0
Headache	1 (2%)	0	0

Note: Includes adverse events with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
[1] Adverse events are counted once for each patient within each Preferred Term; the adverse event with the highest intensity is presented.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_7.sas 27MAY2015 04:58

Table 8.7
Summary of Adverse Events Starting On-Treatment, by Maximum Intensity

Primary System Organ Class/ Preferred Term	Duodart (N=59) Mild	Moderate	Severe
Renal and Urinary Disorders	1 (2%)	0	0
Dysuria	1 (2%)	0	0
Reproductive System and Breast Disorders	1 (2%)	0	0
Ejaculation Disorder	1 (2%)	0	0
Respiratory, Thoracic and Mediastinal Disorders	0	1 (2%)	0
Nasal Congestion	0	1 (2%)	0
Skin and Subcutaneous Tissue Disorders	1 (2%)	0	0
Pruritus	1 (2%)	0	0
Vascular Disorders	0	1 (2%)	0
Hypotension	0	1 (2%)	0

Note: Includes adverse events with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
[1] Adverse events are counted once for each patient within each Preferred Term; the adverse event with the highest intensity is presented.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_7.sas 27MAY2015 04:58

Table 8.8
Summary of Most Common Adverse Events Starting On-Treatment

NO DATA TO DISPLAY

Note: Includes adverse events with onset on or after the first dose of study treatment (but before the treatment stop date if non-missing, or with a missing onset date.
Note: The most common adverse events are those Preferred Terms occurring in at least 5% of the patients.
Note: Number (%) of patients with AEs, sorted on descending frequency for Preferred Term.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_8.sas 27MAY2015 04:58

Table 8.9
Summary of Most Common Non-Serious Adverse Events Starting On-Treatment

NO DATA TO DISPLAY

Note: Includes non-serious adverse events with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
Note: The most common non-serious adverse events are those Preferred Terms occurring in at least 5% of the patients.
Note: Number (%) of patients with AEs, sorted on descending frequency for Preferred Term.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_9.sas 27MAY2015 04:58

Table 8.10
Summary of Treatment Related Adverse Events Starting On-Treatment

Primary System Organ Class/ Preferred Term	Duodart (N=59) #AE	#Sub	(%)
Any Treatment Related Adverse Event	8	3	(5%)
Nervous System Disorders	4	2	(3%)
Dizziness	3	1	(2%)
Headache	1	1	(2%)
Reproductive System and Breast Disorders	1	1	(2%)
Ejaculation Disorder	1	1	(2%)
Respiratory, Thoracic and Mediastinal Disorders	1	1	(2%)
Nasal Congestion	1	1	(2%)
Skin and Subcutaneous Tissue Disorders	1	1	(2%)
Pruritus	1	1	(2%)
Vascular Disorders	1	1	(2%)
Hypotension	1	1	(2%)

Note: Includes treatment related adverse events with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date. Treatment related AEs includes events which the investigator classified as having a reasonable possibility of being caused by the investigational product or whose classification is missing.
Note: Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_10.sas 27MAY2015 04:58

Table 8.11
Summary of Treatment Related Adverse Events Starting Post-Treatment

Primary System Organ Class/ Preferred Term	Duodart (N=59) #AE	#Sub (%)
Any Treatment Related Adverse Event	1	1 (2%)
Vascular Disorders	1	1 (2%)
Hypotension	1	1 (2%)

Note: Includes treatment related adverse events with onset after the treatment stop date. Treatment related AEs includes events which the investigator classified as having a reasonable possibility of being caused by the investigational product or whose classification is missing.
Note: Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_11.sas 27MAY2015 04:58

Table 8.12
Summary of Serious Adverse Events Starting On-Treatment

Primary System Organ Class/ Preferred Term	Duodart (N=59) #AE	#Sub	(%)
Any Serious Adverse Event	1	1	(2%)
Investigations	1	1	(2%)
Hepatic Enzyme Increased	1	1	(2%)

Note: Includes serious adverse events with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
Note: Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_12.sas 27MAY2015 04:58

Table 8.13
Summary of Serious Adverse Events Starting Post-Treatment

Primary System Organ Class/ Preferred Term	Duodart (N=59) #AE	#Sub (%)
Any Serious Adverse Event	1	1 (2%)
Vascular Disorders	1	1 (2%)
Hypotension	1	1 (2%)

Note: Includes Serious adverse events with onset after the treatment stop date.
Note: Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_13.sas 27MAY2015 04:58

Table 8.14
Summary of Fatal Adverse Events Starting On-Treatment

NO DATA TO DISPLAY

Note: Includes fatal adverse events with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_14.sas 27MAY2015 04:58

Table 8.15
Summary of Treatment Related Serious Adverse Events Starting On-Treatment

NO DATA TO DISPLAY

Note: Includes treatment related serious adverse events with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
Treatment related AEs include events which the investigator classified as having a reasonable possibility of being caused by the investigational product or whose classification is missing.
Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_15.sas 27MAY2015 04:58

Table 8.16
Summary of Adverse Events Starting On-Treatment Leading to Withdrawal from the Study

Primary System Organ Class/ Preferred Term	Duodart (N=59) #AE	#Sub	(%)
Any AE Leading to Withdrawal	2	2	(3%)
Investigations	1	1	(2%)
Hepatic Enzyme Increased	1	1	(2%)
Nervous System Disorders	1	1	(2%)
Headache	1	1	(2%)

Note: Includes adverse events leading to withdrawal from the study and with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_16.sas 27MAY2015 04:58

Table 8.17

Summary of Any Treatment Related AE Starting On-Treatment Leading to Withdrawal from the Study

Primary System Organ Class/ Preferred Term	Duodart (N=59) #AE	#Sub	(%)
Any Treatment Related AE Leading to Withdrawal	1	1	(2%)
Nervous System Disorders	1	1	(2%)
Headache	1	1	(2%)

Note: Includes treatment related adverse events leading to withdrawal from the study and with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
Treatment related AEs includes events which the investigator classified as having a reasonable possibility of being caused by the investigational product or whose classification is missing.
Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_17.sas 27MAY2015 04:58

Table 8.18

Summary of Any Serious AE Starting On-Treatment Leading to Withdrawal from the Study

Primary System Organ Class/ Preferred Term	Duodart (N=59) #AE	#Sub (%)
Any Serious AE Leading to Withdrawal	1	1 (2%)
Investigations	1	1 (2%)
Hepatic Enzyme Increased	1	1 (2%)

Note: Includes serious adverse events leading to withdrawal from the study and with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_18.sas 27MAY2015 04:58

Table 8.19
Summary of Adverse Events Starting On-Treatment Leading to Permanent Discontinuation of the Study Treatment

Primary System Organ Class/ Preferred Term	Duodart (N=59) #AE	#Sub (%)
Any Adverse Events Leading to Permanent Discontinuation	2	2 (3%)
Investigations	1	1 (2%)
Hepatic Enzyme Increased	1	1 (2%)
Nervous System Disorders	1	1 (2%)
Headache	1	1 (2%)

Note: Includes adverse events leading to permanent discontinuation of the study treatment and with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_19.sas 27MAY2015 04:58

Table 8.20
Summary of Treatment Related Adverse Events Starting On-Treatment Leading to Permanent Discontinuation of the Study Treatment

Primary System Organ Class/ Preferred Term	Duodart (N=59) #AE	#Sub (%)
Any Treatment Related AEs Leading to Permanent Discontinuation	1	1 (2%)
Nervous System Disorders	1	1 (2%)
Headache	1	1 (2%)

Note: Includes treatment related adverse events leading to permanent discontinuation of the study treatment and with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
Treatment related AEs includes events which the investigator classified as having a reasonable possibility of being caused by the investigational product or whose classification is missing.
Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_20.sas 27MAY2015 04:58

Table 8.21
Summary of Serious Adverse Events Starting On-Treatment Leading to Permanent Discontinuation of the Study Treatment

Primary System Organ Class/ Preferred Term	Duodart (N=59) #AE	#Sub (%)
Any Serious AEs Leading to Permanent Discontinuation	1	1 (2%)
Investigations	1	1 (2%)
Hepatic Enzyme Increased	1	1 (2%)

Note: Includes serious adverse events leading to permanent discontinuation of the study treatment and with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
Number (%) of patients with AEs, sorted on descending frequency for System Organ Class and Preferred Term.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_21.sas 27MAY2015 04:58

Table 8.22
Summary of Adverse Events Starting On-Treatment, by Descending Frequency

Preferred Term	Duodart (N=59) #AE	#Sub (%)
Any Adverse Event	19	13 (22%)
Dizziness	4	2 (3%)
Fatigue	3	2 (3%)
Alanine Aminotransferase Increased	1	1 (2%)
Bronchitis	1	1 (2%)
Conjunctivitis	1	1 (2%)
Dysuria	1	1 (2%)
Ejaculation Disorder	1	1 (2%)
Headache	1	1 (2%)
Hepatic Enzyme Increased	1	1 (2%)

Note: Includes adverse events with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_22.sas 27MAY2015 04:58

Table 8.22
Summary of Adverse Events Starting On-Treatment, by Descending Frequency

Preferred Term	Duodart (N=59) #AE	#Sub	(%)
Hypotension	1	1	(2%)
Nasal Congestion	1	1	(2%)
Peripheral Swelling	1	1	(2%)
Pharyngitis	1	1	(2%)
Pruritus	1	1	(2%)

Note: Includes adverse events with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_22.sas 27MAY2015 04:58

Table 8.23
Summary of Sexual and Breast Adverse Events of Special Interest Starting On-Treatment

Special Interest Event/ Preferred Term	Duodart (N=59) #AE	#Sub	(%)
Any Sexual or Breast AE of Special Interest	1	1	(2%)
Ejaculation Disorders	1	1	(2%)
Ejaculation Disorder	1	1	(2%)

Note: Includes adverse events with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.

Table 8.24

Summary of Sexual and Breast Adverse Events of Special Interest Starting Post-Treatment

NO DATA TO DISPLAY

Note: Includes adverse events with onset after the last dose of study treatment.

Table 8.25
Summary of Special Interest Adverse Event Starting On-Treatment: Prostate Cancer

NO DATA TO DISPLAY

Note: Includes adverse events with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_25.sas 27MAY2015 04:58

Table 8.26
Summary of Special Interest Adverse Event Starting Post-Treatment: Prostate Cancer

NO DATA TO DISPLAY

Note: Includes adverse events with onset after last dose of study treatment.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_26.sas 27MAY2015 04:58

Table 8.27
Summary of Cardiovascular Adverse Events of Special Interest Starting On-Treatment

NO DATA TO DISPLAY

Note: Includes adverse events with onset on or after the first dose of study treatment (but on or before the treatment stop date, if that is non-missing), or with a missing onset date.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_27.sas 27MAY2015 04:58

Table 8.28
Summary of Cardiovascular Adverse Events of Special Interest Starting Post-Treatment

NO DATA TO DISPLAY

Note: Includes adverse events with onset after last dose of study treatment.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_28.sas 27MAY2015 04:59

Table 8.29
Summary of Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hematology	Basophils/Leukocytes (%)	Screening	59	0.651	0.2605	0.630	0.13	1.35
		Visit 3 (Month 3)	54	0.709	0.4474	0.605	0.10	2.06
		Visit 5 (Month 6)	52	0.685	0.3577	0.635	0.10	1.83
		Final Value	54	0.681	0.3520	0.625	0.10	1.83
	Eosinophils/ Leukocytes (%)	Screening	59	3.541	3.2462	2.430	0.07	14.56
		Visit 3 (Month 3)	54	4.421	3.4948	3.300	0.82	15.86
		Visit 5 (Month 6)	52	3.923	3.3191	2.920	0.38	16.44
		Final Value	54	3.930	3.2888	2.920	0.38	16.44

Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.29
Summary of Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hematology	Ery. Mean Corpuscular HGB Concentration (g/L)	Screening	59	328.1	13.39	325.0	298	372
		Visit 3 (Month 3)	54	327.3	11.81	327.5	296	354
		Visit 5 (Month 6)	52	326.4	15.73	325.0	293	364
		Final Value	54	326.0	15.59	324.5	293	364
	Ery. Mean Corpuscular Hemoglobin (pg)	Screening	59	29.50	2.509	30.20	21.7	33.7
		Visit 3 (Month 3)	54	29.49	2.644	29.85	20.6	34.3
		Visit 5 (Month 6)	52	29.56	2.658	30.30	21.0	34.6
		Final Value	54	29.61	2.631	30.30	21.0	34.6

Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.29
Summary of Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hematology	Ery. Mean Corpuscular Volume (fL)	Screening	59	89.87	6.691	91.50	69.3	99.7
		Visit 3 (Month 3)	54	90.02	6.466	91.15	69.6	102.1
		Visit 5 (Month 6)	52	90.50	6.582	91.60	68.1	101.2
		Final Value	54	90.80	6.676	92.00	68.1	102.1
	Erythrocytes (10^12/L)	Screening	59	4.728	0.5616	4.750	3.42	6.57
		Visit 3 (Month 3)	54	4.781	0.5439	4.725	3.86	6.84
		Visit 5 (Month 6)	52	4.741	0.5558	4.730	3.75	6.60
		Final Value	54	4.744	0.5470	4.730	3.75	6.60

Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.29
Summary of Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hematology	Erythrocytes Distribution Width (%)	Screening	59	12.00	1.493	11.70	9.5	17.2
		Visit 3 (Month 3)	54	12.19	1.217	12.20	9.7	15.2
		Visit 5 (Month 6)	52	12.29	1.276	12.40	9.4	16.4
		Final Value	54	12.28	1.253	12.40	9.4	16.4
	Hematocrit (1)	Screening	59	0.4226	0.03932	0.4270	0.315	0.529
		Visit 3 (Month 3)	54	0.4280	0.03336	0.4275	0.351	0.508
		Visit 5 (Month 6)	52	0.4267	0.03624	0.4250	0.346	0.502
		Final Value	54	0.4284	0.03673	0.4290	0.346	0.502

Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.29
Summary of Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hematology	Hemoglobin (g/L)	Screening	59	138.5	12.68	140.0	103	167
		Visit 3 (Month 3)	54	140.0	10.68	139.5	114	162
		Visit 5 (Month 6)	52	139.1	10.57	139.0	117	158
		Final Value	54	139.4	10.56	140.0	117	158
	Leukocytes (10 ^9/L)	Screening	59	7.756	1.9583	7.150	4.21	14.13
		Visit 3 (Month 3)	54	7.414	1.6792	7.255	4.36	12.11
		Visit 5 (Month 6)	52	7.362	1.5143	7.420	4.73	12.05
		Final Value	54	7.346	1.5121	7.420	4.73	12.05

Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.29
Summary of Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hematology	Lymphocytes/ Leukocytes (%)	Screening	59	28.79	8.270	28.00	12.2	50.8
		Visit 3 (Month 3)	54	29.96	8.152	29.40	15.1	58.1
		Visit 5 (Month 6)	52	30.97	7.349	30.55	15.4	46.2
		Final Value	54	31.04	7.539	30.55	15.4	46.2
	Monocytes/Leukocytes (%)	Screening	59	8.126	1.8991	7.800	2.83	13.11
		Visit 3 (Month 3)	54	8.061	1.7226	7.975	4.85	12.14
		Visit 5 (Month 6)	52	7.892	1.6604	7.950	4.56	11.30
		Final Value	54	7.932	1.6539	7.980	4.56	11.30

Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.29
Summary of Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hematology	Neutrophils/ Leukocytes (%)	Screening	59	58.91	9.418	58.90	39.2	84.6
		Visit 3 (Month 3)	54	56.84	8.834	56.75	30.2	75.0
		Visit 5 (Month 6)	52	56.53	8.078	55.25	41.3	73.8
		Final Value	54	56.41	8.176	55.25	41.3	73.8
	Platelets (10 ^9/L)	Screening	59	236.6	49.83	233.0	116	363
		Visit 3 (Month 3)	54	228.9	51.37	234.0	139	401
		Visit 5 (Month 6)	52	230.1	45.96	227.0	127	351
		Final Value	54	229.1	46.00	227.0	127	351

Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.29
Summary of Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Blood Chemistry	Alanine Aminotransferase (IU/L)	Screening	59	26.3	12.59	23.0	9	71
		Visit 1 (Month 1)	56	27.3	26.14	22.5	6	195
		Visit 3 (Month 3)	54	26.9	16.26	24.0	7	86
		Visit 5 (Month 6)	52	25.3	11.32	22.5	8	71
		Final Value	56	26.3	13.58	22.5	8	85
	Aspartate Aminotransferase (IU/L)	Screening	59	26.0	12.12	23.0	13	95
		Visit 1 (Month 1)	56	25.7	19.98	22.0	12	164
		Visit 3 (Month 3)	54	26.0	10.09	22.5	14	75

Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.29
Summary of Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Blood Chemistry	Aspartate Aminotransferase (IU/L)	Visit 5 (Month 6)	52	24.8	6.90	23.0	14	51
		Final Value	56	25.8	9.57	23.0	14	75
	Creatinine (umol/L)	Screening	59	84.88	19.507	81.00	57.0	176.0
		Visit 1 (Month 1)	56	83.16	15.395	81.00	59.0	139.0
		Visit 3 (Month 3)	54	84.54	16.617	82.50	57.0	128.0
		Visit 5 (Month 6)	52	87.23	17.992	86.00	57.0	145.0
		Final Value	56	87.32	17.469	86.00	57.0	145.0
	Glucose (mmol/L)	Screening	59	6.00	1.167	5.60	4.4	10.7

Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.29
Summary of Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Blood Chemistry	Glucose (mmol/L)	Visit 1 (Month 1)	56	6.02	1.005	5.70	3.6	8.7
		Visit 3 (Month 3)	54	5.92	0.729	5.70	4.5	8.3
		Visit 5 (Month 6)	52	6.00	0.890	5.70	4.7	10.2
		Final Value	56	5.98	0.867	5.70	4.7	10.2
	Potassium (mmol/L)	Screening	59	4.07	0.341	4.10	3.0	4.8
		Visit 3 (Month 3)	54	4.21	0.351	4.20	3.4	5.3
		Visit 5 (Month 6)	52	4.23	0.315	4.30	3.5	4.9
		Final Value	54	4.22	0.314	4.30	3.5	4.9

Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.29
Summary of Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Blood Chemistry	Protein (g/L)	Screening	59	72.7	3.84	72.0	65	82
		Visit 1 (Month 1)	56	73.0	4.63	72.0	61	83
		Visit 3 (Month 3)	54	73.9	4.73	74.0	64	86
		Visit 5 (Month 6)	52	73.6	4.14	74.0	64	82
		Final Value	56	73.6	4.09	74.0	64	82
	Sodium (mmol/L)	Screening	59	139.9	2.60	140.0	129	144
		Visit 3 (Month 3)	54	140.1	1.78	140.0	135	144
		Visit 5 (Month 6)	52	140.3	1.86	140.0	136	145

Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.29
Summary of Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Blood Chemistry	Sodium (mmol/L)	Final Value	54	140.3	1.86	140.0	136	145
	Urea (mmol/L)	Screening	59	5.74	1.371	5.50	3.0	9.9
		Visit 1 (Month 1)	56	5.52	1.352	5.25	2.8	8.8
		Visit 3 (Month 3)	54	5.56	1.323	5.50	3.0	8.8
		Visit 5 (Month 6)	52	5.83	1.612	5.80	3.2	10.1
		Final Value	56	5.85	1.619	5.80	3.2	10.1

Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.29
Summary of Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Urinalysis	pH	Screening	59	5.9	0.91	6.0	5	8
		Visit 3 (Month 3)	54	5.8	1.06	5.0	5	9
		Visit 5 (Month 6)	52	5.7	0.88	5.0	5	8
		Final Value	54	5.7	0.87	5.0	5	8

Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.30
Summary of Change from Baseline in Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hematology	Basophils/Leukocytes (%)	Visit 3 (Month 3)	54	0.071	0.4430	-0.025	-0.54	1.50
		Visit 5 (Month 6)	52	0.040	0.3964	-0.015	-0.89	0.85
		Final Value	54	0.042	0.3914	-0.015	-0.89	0.85
	Eosinophils/Leukocytes (%)	Visit 3 (Month 3)	54	0.681	2.9102	0.170	-6.39	10.32
		Visit 5 (Month 6)	52	0.214	2.2324	0.390	-6.30	5.52
		Final Value	54	0.190	2.1959	0.300	-6.30	5.52
	Ery. Mean Corpuscular HGB Concentration (g/L)	Visit 3 (Month 3)	54	-0.7	13.74	-1.0	-26	38
		Visit 5 (Month 6)	52	-1.6	17.60	-3.0	-35	40
		Final Value	54	-2.0	17.43	-3.5	-35	40

Note: Change from baseline is post-baseline value minus baseline value.
The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.30
Summary of Change from Baseline in Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hematology	Ery. Mean Corpuscular Hemoglobin (pg)	Visit 3 (Month 3)	54	0.09	0.899	0.05	-2.2	1.6
		Visit 5 (Month 6)	52	0.23	0.763	0.20	-1.4	2.2
		Final Value	54	0.21	0.755	0.20	-1.4	2.2
	Ery. Mean Corpuscular Volume (fL)	Visit 3 (Month 3)	54	0.44	3.316	0.45	-10.0	6.7
		Visit 5 (Month 6)	52	1.17	4.053	1.50	-6.8	10.5
		Final Value	54	1.23	3.996	1.55	-6.8	10.5
	Erythrocytes (10 ^12/L)	Visit 3 (Month 3)	54	0.051	0.2439	0.045	-0.59	0.50
		Visit 5 (Month 6)	52	0.011	0.2499	0.040	-0.51	0.46
		Final Value	54	0.014	0.2455	0.055	-0.51	0.46

Note: Change from baseline is post-baseline value minus baseline value.
The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.
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Table 8.30
Summary of Change from Baseline in Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hematology	Erythrocytes Distribution Width (%)	Visit 3 (Month 3)	54	0.16	1.817	0.25	-5.3	2.9
		Visit 5 (Month 6)	52	0.30	1.435	0.45	-4.0	3.2
		Final Value	54	0.26	1.436	0.40	-4.0	3.2
	Hematocrit (1)	Visit 3 (Month 3)	54	0.0068	0.02579	0.0065	-0.058	0.056
		Visit 5 (Month 6)	52	0.0067	0.02673	0.0110	-0.048	0.067
		Final Value	54	0.0072	0.02638	0.0135	-0.048	0.067
	Hemoglobin (g/L)	Visit 3 (Month 3)	54	1.9	5.95	1.5	-14	13
		Visit 5 (Month 6)	52	1.4	7.06	1.5	-14	14
		Final Value	54	1.4	6.93	1.5	-14	14

Note: Change from baseline is post-baseline value minus baseline value.
The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.
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Table 8.30
Summary of Change from Baseline in Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hematology	Leukocytes (10 ^9/L)	Visit 3 (Month 3)	54	-0.300	1.5817	-0.415	-4.52	4.17
		Visit 5 (Month 6)	52	-0.325	1.5236	-0.085	-3.54	3.36
		Final Value	54	-0.369	1.5193	-0.245	-3.54	3.36
	Lymphocytes/Leukocytes (%)	Visit 3 (Month 3)	54	1.43	6.489	1.05	-12.0	20.0
		Visit 5 (Month 6)	52	2.58	7.487	1.35	-11.0	25.7
		Final Value	54	2.51	7.411	1.35	-11.0	25.7
	Monocytes/Leukocytes (%)	Visit 3 (Month 3)	54	-0.060	1.8910	0.055	-5.52	6.98
		Visit 5 (Month 6)	52	-0.140	2.0725	-0.055	-4.67	8.47
		Final Value	54	-0.189	2.0541	-0.125	-4.67	8.47

Note: Change from baseline is post-baseline value minus baseline value.
The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.
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Table 8.30
Summary of Change from Baseline in Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Hematology	Neutrophils/Leukocytes (%)	Visit 3 (Month 3)	54	-2.13	8.244	-1.60	-32.0	13.9
		Visit 5 (Month 6)	52	-2.71	9.169	-1.10	-26.5	18.4
		Final Value	54	-2.57	9.045	-1.10	-26.5	18.4
	Platelets (10 ^9/L)	Visit 3 (Month 3)	54	-7.9	34.26	-3.0	-121	89
		Visit 5 (Month 6)	52	-7.6	29.92	-7.0	-93	61
		Final Value	54	-7.7	29.42	-7.0	-93	61

Note: Change from baseline is post-baseline value minus baseline value.
The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.30
Summary of Change from Baseline in Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Blood Chemistry	Alanine Aminotransferase (IU/L)	Visit 1 (Month 1)	56	0.9	25.24	-1.0	-47	161
		Visit 3 (Month 3)	54	0.2	13.93	0.0	-48	51
		Visit 5 (Month 6)	52	-1.3	10.91	-0.5	-35	21
		Final Value	56	-0.1	12.67	0.0	-35	51
	Aspartate Aminotransferase (IU/L)	Visit 1 (Month 1)	56	-0.5	11.95	-1.0	-27	69
		Visit 3 (Month 3)	54	-0.4	8.46	0.5	-21	20
		Visit 5 (Month 6)	52	-0.2	7.48	0.5	-23	14
		Final Value	56	-0.4	7.75	0.5	-23	14
	Creatinine (umol/L)	Visit 1 (Month 1)	56	0.41	11.178	-2.00	-21.0	29.0

Note: Change from baseline is post-baseline value minus baseline value.
The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.
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Table 8.30
Summary of Change from Baseline in Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Blood Chemistry	Creatinine (umol/L)	Visit 3 (Month 3)	54	1.94	13.117	1.00	-29.0	35.0
		Visit 5 (Month 6)	52	4.35	11.467	4.50	-22.0	30.0
		Final Value	56	4.57	11.502	4.00	-22.0	30.0
	Glucose (mmol/L)	Visit 1 (Month 1)	56	0.08	0.987	0.10	-3.6	2.5
		Visit 3 (Month 3)	54	-0.02	0.958	0.20	-3.0	2.2
		Visit 5 (Month 6)	52	0.04	1.044	0.20	-4.3	2.6
		Final Value	56	0.05	1.008	0.20	-4.3	2.6
	Potassium (mmol/L)	Visit 3 (Month 3)	54	0.16	0.411	0.20	-0.9	0.9
		Visit 5 (Month 6)	52	0.16	0.350	0.20	-0.5	1.0

Note: Change from baseline is post-baseline value minus baseline value.
The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.
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Table 8.30
Summary of Change from Baseline in Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Blood Chemistry	Potassium (mmol/L)	Final Value	54	0.16	0.345	0.20	-0.5	1.0
	Protein (g/L)	Visit 1 (Month 1)	56	0.3	3.98	0.0	-6	14
		Visit 3 (Month 3)	54	1.1	4.25	1.0	-12	13
		Visit 5 (Month 6)	52	1.0	3.74	0.5	-7	10
		Final Value	56	0.9	3.76	0.0	-7	10
	Sodium (mmol/L)	Visit 3 (Month 3)	54	0.0	3.07	-0.5	-6	11
		Visit 5 (Month 6)	52	0.3	2.56	0.0	-5	10
		Final Value	54	0.2	2.60	0.0	-5	10
	Urea (mmol/L)	Visit 1 (Month 1)	56	-0.16	1.104	-0.15	-3.0	2.0

Note: Change from baseline is post-baseline value minus baseline value.
The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.
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Table 8.30
Summary of Change from Baseline in Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Blood Chemistry	Urea (mmol/L)	Visit 3 (Month 3)	54	-0.07	1.315	-0.15	-4.0	3.5
		Visit 5 (Month 6)	52	0.24	1.590	0.15	-3.9	4.0
		Final Value	56	0.17	1.563	0.00	-3.9	4.0

Note: Change from baseline is post-baseline value minus baseline value.
The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.30
Summary of Change from Baseline in Laboratory Data

Treatment: Duodart(N=59)

Lab Category	Lab Test (Unit)	Planned Relative Time	n	Mean	SD	Median	Min.	Max.
Urinalysis	pH	Visit 3 (Month 3)	54	-0.1	1.25	0.0	-3	4
		Visit 5 (Month 6)	52	-0.2	1.02	0.0	-2	3
		Final Value	54	-0.2	1.02	0.0	-2	3

Note: Change from baseline is post-baseline value minus baseline value.
The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.31
Summary of Baseline Abnormal Laboratory Values

	Duodart (N=59)
Any Abnormality	54/56 (96%)
Hematology	
Basophils/Leukocytes (%)	0/54 (0%)
Eosinophils/Leukocytes (%)	8/54 (15%)
Ery. Mean Corpuscular HGB Concentration (g/L)	10/54 (19%)
Ery. Mean Corpuscular Hemoglobin (pg)	18/54 (33%)
Ery. Mean Corpuscular Volume (fL)	12/54 (22%)
Erythrocytes (10 ^12/L)	5/54 (9%)
Erythrocytes Distribution Width (%)	50/54 (93%)
Hematocrit (1)	6/54 (11%)
Hemoglobin (g/L)	5/54 (9%)
Leukocytes (10 ^9/L)	7/54 (13%)
Lymphocytes/Leukocytes (%)	1/54 (2%)
Monocytes/Leukocytes (%)	2/54 (4%)
Neutrophils/Leukocytes (%)	13/54 (24%)
Platelets (10 ^9/L)	1/54 (2%)

Note: Only patients with a baseline value and at least one post-baseline value are included in this display.

Table 8.31
Summary of Baseline Abnormal Laboratory Values

	Duodart (N=59)
Blood Chemistry	
Alanine Aminotransferase (IU/L)	8/56 (14%)
Aspartate Aminotransferase (IU/L)	7/56 (13%)
Creatinine (umol/L)	5/56 (9%)
Glucose (mmol/L)	9/56 (16%)
Potassium (mmol/L)	2/54 (4%)
Protein (g/L)	0/56 (0%)
Sodium (mmol/L)	1/54 (2%)
Urea (mmol/L)	2/56 (4%)

Note: Only patients with a baseline value and at least one post-baseline value are included in this display.

Table 8.32

Summary of Shift in Laboratory Values: Normal at Baseline to Abnormal at Any Time Post-Baseline

	Duodart (N=59)
Any Abnormality	44/56 (79%)
Hematology	
Basophils/Leukocytes (%)	0/54 (0%)
Eosinophils/Leukocytes (%)	5/46 (11%)
Ery. Mean Corpuscular HGB Concentration (g/L)	22/44 (50%)
Ery. Mean Corpuscular Hemoglobin (pg)	6/36 (17%)
Ery. Mean Corpuscular Volume (fL)	4/42 (10%)
Erythrocytes (10 ^12/L)	3/49 (6%)
Erythrocytes Distribution Width (%)	3/ 4 (75%)
Hematocrit (1)	7/48 (15%)
Hemoglobin (g/L)	2/49 (4%)
Leukocytes (10 ^9/L)	7/47 (15%)
Lymphocytes/Leukocytes (%)	1/53 (2%)
Monocytes/Leukocytes (%)	1/52 (2%)
Neutrophils/Leukocytes (%)	5/41 (12%)
Platelets (10 ^9/L)	1/53 (2%)

Note: Only patients with a normal baseline and at least one post-baseline value are included in this display.

Table 8.32

Summary of Shift in Laboratory Values: Normal at Baseline to Abnormal at Any Time Post-Baseline

	Duodart (N=59)
Blood Chemistry	
Alanine Aminotransferase (IU/L)	9/48 (19%)
Aspartate Aminotransferase (IU/L)	6/49 (12%)
Creatinine (umol/L)	9/51 (18%)
Glucose (mmol/L)	8/47 (17%)
Potassium (mmol/L)	1/52 (2%)
Protein (g/L)	4/56 (7%)
Sodium (mmol/L)	0/53 (0%)
Urea (mmol/L)	7/54 (13%)

Note: Only patients with a normal baseline and at least one post-baseline value are included in this display.

Table 8.33

Summary of Shift in Laboratory Values: Normal at Baseline to High at Any Time Post-Baseline

	Duodart (N=59)
Any Abnormality	40/56 (71%)
Hematology	
Basophils/Leukocytes (%)	0/54 (0%)
Eosinophils/Leukocytes (%)	5/46 (11%)
Ery. Mean Corpuscular HGB Concentration (g/L)	4/44 (9%)
Ery. Mean Corpuscular Hemoglobin (pg)	5/36 (14%)
Ery. Mean Corpuscular Volume (fL)	4/42 (10%)
Erythrocytes (10 ^12/L)	1/49 (2%)
Erythrocytes Distribution Width (%)	0/ 4 (0%)
Hematocrit (1)	3/48 (6%)
Hemoglobin (g/L)	1/49 (2%)
Leukocytes (10 ^9/L)	7/47 (15%)
Lymphocytes/Leukocytes (%)	1/53 (2%)
Monocytes/Leukocytes (%)	1/52 (2%)
Neutrophils/Leukocytes (%)	4/41 (10%)
Platelets (10 ^9/L)	0/53 (0%)

Note: Only patients with a normal baseline and at least one post-baseline value are included in this display.

Table 8.33

Summary of Shift in Laboratory Values: Normal at Baseline to High at Any Time Post-Baseline

	Duodart (N=59)
Blood Chemistry	
Alanine Aminotransferase (IU/L)	9/48 (19%)
Aspartate Aminotransferase (IU/L)	6/49 (12%)
Creatinine (umol/L)	9/51 (18%)
Glucose (mmol/L)	7/47 (15%)
Potassium (mmol/L)	0/52 (0%)
Protein (g/L)	0/56 (0%)
Sodium (mmol/L)	0/53 (0%)
Urea (mmol/L)	7/54 (13%)

Note: Only patients with a normal baseline and at least one post-baseline value are included in this display.

Table 8.34

Summary of Shift in Laboratory Values: Normal at Baseline to Low at Any Time Post-Baseline

	Duodart (N=59)
Any Abnormality	30/56 (54%)
Hematology	
Basophils/Leukocytes (%)	0/54 (0%)
Eosinophils/Leukocytes (%)	0/46 (0%)
Ery. Mean Corpuscular HGB Concentration (g/L)	18/44 (41%)
Ery. Mean Corpuscular Hemoglobin (pg)	1/36 (3%)
Ery. Mean Corpuscular Volume (fL)	0/42 (0%)
Erythrocytes (10 ^12/L)	2/49 (4%)
Erythrocytes Distribution Width (%)	3/ 4 (75%)
Hematocrit (1)	4/48 (8%)
Hemoglobin (g/L)	1/49 (2%)
Leukocytes (10 ^9/L)	0/47 (0%)
Lymphocytes/Leukocytes (%)	0/53 (0%)
Monocytes/Leukocytes (%)	0/52 (0%)
Neutrophils/Leukocytes (%)	1/41 (2%)
Platelets (10 ^9/L)	1/53 (2%)

Note: Only patients with a normal baseline and at least one post-baseline value are included in this display.

Table 8.34

Summary of Shift in Laboratory Values: Normal at Baseline to Low at Any Time Post-Baseline

	Duodart (N=59)
Blood Chemistry	
Alanine Aminotransferase (IU/L)	0/48 (0%)
Aspartate Aminotransferase (IU/L)	0/49 (0%)
Creatinine (umol/L)	0/51 (0%)
Glucose (mmol/L)	1/47 (2%)
Potassium (mmol/L)	1/52 (2%)
Protein (g/L)	4/56 (7%)
Sodium (mmol/L)	0/53 (0%)
Urea (mmol/L)	0/54 (0%)

Note: Only patients with a normal baseline and at least one post-baseline value are included in this display.

Table 8.35

Summary of Shift in Laboratory Values: Normal or Low at Baseline to High at Any Time Post-Baseline

	Duodart (N=59)
Any Abnormality	40/56 (71%)
Hematology	
Basophils/Leukocytes (%)	0/54 (0%)
Eosinophils/Leukocytes (%)	5/46 (11%)
Ery. Mean Corpuscular HGB Concentration (g/L)	4/53 (8%)
Ery. Mean Corpuscular Hemoglobin (pg)	5/44 (11%)
Ery. Mean Corpuscular Volume (fL)	4/46 (9%)
Erythrocytes (10 ^12/L)	1/53 (2%)
Erythrocytes Distribution Width (%)	0/54 (0%)
Hematocrit (1)	3/52 (6%)
Hemoglobin (g/L)	1/53 (2%)
Leukocytes (10 ^9/L)	7/48 (15%)
Lymphocytes/Leukocytes (%)	1/53 (2%)
Monocytes/Leukocytes (%)	1/52 (2%)
Neutrophils/Leukocytes (%)	4/41 (10%)
Platelets (10 ^9/L)	0/54 (0%)

Note: Only patients with a normal or low at baseline and at least one post-baseline value are included in this display.

Table 8.35

Summary of Shift in Laboratory Values: Normal or Low at Baseline to High at Any Time Post-Baseline

	Duodart (N=59)
Blood Chemistry	
Alanine Aminotransferase (IU/L)	9/48 (19%)
Aspartate Aminotransferase (IU/L)	6/49 (12%)
Creatinine (umol/L)	9/51 (18%)
Glucose (mmol/L)	7/47 (15%)
Potassium (mmol/L)	0/54 (0%)
Protein (g/L)	0/56 (0%)
Sodium (mmol/L)	0/54 (0%)
Urea (mmol/L)	7/54 (13%)

Note: Only patients with a normal or low at baseline and at least one post-baseline value are included in this display.

Table 8.36

Summary of Shift in Laboratory Values: Normal or High at Baseline to Low at Any Time Post-Baseline

	Duodart (N=59)
Any Abnormality	30/56 (54%)
Hematology	
Basophils/Leukocytes (%)	0/54 (0%)
Eosinophils/Leukocytes (%)	0/54 (0%)
Ery. Mean Corpuscular HGB Concentration (g/L)	18/45 (40%)
Ery. Mean Corpuscular Hemoglobin (pg)	1/46 (2%)
Ery. Mean Corpuscular Volume (fL)	0/50 (0%)
Erythrocytes (10 ^12/L)	2/50 (4%)
Erythrocytes Distribution Width (%)	3/ 4 (75%)
Hematocrit (1)	4/50 (8%)
Hemoglobin (g/L)	1/50 (2%)
Leukocytes (10 ^9/L)	0/53 (0%)
Lymphocytes/Leukocytes (%)	0/54 (0%)
Monocytes/Leukocytes (%)	0/54 (0%)
Neutrophils/Leukocytes (%)	1/54 (2%)
Platelets (10 ^9/L)	1/53 (2%)

Note: Only patients with a normal or high at baseline and at least one post-baseline value are included in this display.

Table 8.36

Summary of Shift in Laboratory Values: Normal or High at Baseline to Low at Any Time Post-Baseline

	Duodart (N=59)
Blood Chemistry	
Alanine Aminotransferase (IU/L)	0/56 (0%)
Aspartate Aminotransferase (IU/L)	0/56 (0%)
Creatinine (umol/L)	0/56 (0%)
Glucose (mmol/L)	1/56 (2%)
Potassium (mmol/L)	1/52 (2%)
Protein (g/L)	4/56 (7%)
Sodium (mmol/L)	0/53 (0%)
Urea (mmol/L)	0/56 (0%)

Note: Only patients with a normal or high at baseline and at least one post-baseline value are included in this display.

Table 8.37
Summary of Laboratory Data Transitions: Change from Baseline to Final Assessment

Treatment: Duodart(N=59)

Laboratory Test	Number of patients	--DECREASE-- HL	NL	HN	LL	-NO CHANGE- NN	HH	--INCREASE-- LN	NH	LH
Hematology										
Basophils/Leukocytes (%)	54	0	0	0	0	54	0	0	0	0
Eosinophils/Leukocytes (%)	54	0	0	5	0	43	3	0	3	0
Ery. Mean Corpuscular HGB Concentration (g/L)	54	0	16	0	3	24	1	6	4	0
Ery. Mean Corpuscular Hemoglobin (pg)	54	0	0	3	6	31	7	2	5	0
Ery. Mean Corpuscular Volume (fL)	54	0	0	5	4	39	3	0	3	0
Erythrocytes (10 ^12/L)	54	0	2	0	4	46	1	0	1	0
Erythrocytes Distribution Width (%)	54	0	2	0	49	2	0	1	0	0
Hematocrit (1)	54	0	3	1	2	43	1	2	2	0

Note: L=Low; N=Normal; H=High. The first letter denotes the baseline value and the second letter the value at the final assessment.
Only patients with a baseline and at least one post-baseline value have been included in this display.

Table 8.37
Summary of Laboratory Data Transitions: Change from Baseline to Final Assessment

Treatment: Duodart(N=59)

Laboratory Test	Number of patients	--DECREASE-- HL	NL	HN	LL	-NO CHANGE- NN	HH	LN	--INCREASE-- NH	LH
Hemoglobin (g/L)	54	0	0	1	3	49	0	1	0	0
Leukocytes (10 ^9/L)	54	0	0	5	0	44	1	1	3	0
Lymphocytes/Leukocytes (%)	54	0	0	1	0	53	0	0	0	0
Monocytes/Leukocytes (%)	54	0	0	2	0	52	0	0	0	0
Neutrophils/Leukocytes (%)	54	0	0	10	0	38	3	0	3	0
Platelets (10 ^9/L)	54	0	0	0	1	53	0	0	0	0

Note: L=Low; N=Normal; H=High. The first letter denotes the baseline value and the second letter the value at the final assessment.
Only patients with a baseline and at least one post-baseline value have been included in this display.
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Table 8.37
Summary of Laboratory Data Transitions: Change from Baseline to Final Assessment

Treatment: Duodart(N=59)

Laboratory Test	Number of patients	--DECREASE-- HL	NL	HN	LL	-NO CHANGE- NN	HH	LN	--INCREASE-- NH	LH
Blood Chemistry										
Alanine Aminotransferase (IU/L)	56	0	0	4	0	42	4	0	6	0
Aspartate Aminotransferase (IU/L)	56	0	0	4	0	45	3	0	4	0
Creatinine (umol/L)	56	0	0	3	0	47	2	0	4	0
Glucose (mmol/L)	56	0	0	8	0	42	1	0	5	0
Potassium (mmol/L)	54	0	0	0	0	52	0	2	0	0
Protein (g/L)	56	0	1	0	0	55	0	0	0	0
Sodium (mmol/L)	54	0	0	0	0	53	0	1	0	0
Urea (mmol/L)	56	0	0	1	0	50	1	0	4	0

Note: L=Low; N=Normal; H=High. The first letter denotes the baseline value and the second letter the value at the final assessment.
Only patients with a baseline and at least one post-baseline value have been included in this display.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_37.sas 27MAY2015 04:59

Table 8.38
Summary of Baseline Threshold Laboratory Values

	Duodart (N=59)
Any Threshold Value	2/56 (4%)
Hematology	
Hemoglobin (g/L)	
<0.75 X LLN	0/54 (0%)
Ery. Mean Corpuscular Volume (fL)	
<0.9 X LLN	2/54 (4%)
>1.1 X ULN	0/54 (0%)
Either Threshold	2/54 (4%)
Platelets (10 ^9/L)	
<0.75 X LLN	0/54 (0%)
>1.5 X ULN	0/54 (0%)
Either Threshold	0/54 (0%)
Leukocytes (10 ^9/L)	
<0.5 X LLN	0/54 (0%)
>3.0 X ULN	0/54 (0%)
Either Threshold	0/54 (0%)

Note: Number of patients with a threshold value at baseline among patients with a baseline and at least one post-baseline lab assessment.

Table 8.38
Summary of Baseline Threshold Laboratory Values

	Duodart (N=59)
Blood Chemistry	
Alanine Aminotransferase (IU/L)	
>3.0 X ULN	0/56 (0%)
Aspartate Aminotransferase (IU/L)	
>3.0 X ULN	0/56 (0%)
Creatinine (umol/L)	
<0.5 X LLN	0/56 (0%)
>3.0 X ULN	0/56 (0%)
Either Threshold	0/56 (0%)
Glucose (mmol/L)	
<0.7 X LLN	0/56 (0%)
>1.75 X ULN	0/56 (0%)
Either Threshold	0/56 (0%)
Potassium (mmol/L)	
<0.75 X LLN	0/54 (0%)
>1.4 X ULN	0/54 (0%)

Note: Number of patients with a threshold value at baseline among patients with a baseline and at least one post-baseline lab assessment.

Table 8.38
Summary of Baseline Threshold Laboratory Values

	Duodart (N=59)
Either Threshold	0/54 (0%)
Protein (g/L)	
<0.8 X LLN	0/56 (0%)
>1.15 X ULN	0/56 (0%)
Either Threshold	0/56 (0%)
Sodium (mmol/L)	
<0.9 X LLN	0/54 (0%)
>1.15 X ULN	0/54 (0%)
Either Threshold	0/54 (0%)
Urea (mmol/L)	
<0.5 X LLN	0/56 (0%)
>2.0 X ULN	0/56 (0%)
Either Threshold	0/56 (0%)

Note: Number of patients with a threshold value at baseline among patients with a baseline and at least one post-baseline lab assessment.

Table 8.39
Summary of Threshold Laboratory Values at Any Time Post-Baseline

	Duodart (N=59)
Any Threshold Value	1/56 (2%)
Hematology	
Hemoglobin (g/L)	
<0.75 X LLN	0/54 (0%)
Ery. Mean Corpuscular Volume (fL)	
<0.9 X LLN	0/52 (0%)
>1.1 X ULN	0/52 (0%)
Either Threshold	0/52 (0%)
Platelets (10 ^9/L)	
<0.75 X LLN	0/54 (0%)
>1.5 X ULN	0/54 (0%)
Either Threshold	0/54 (0%)
Leukocytes (10 ^9/L)	
<0.5 X LLN	0/54 (0%)
>3.0 X ULN	0/54 (0%)
Either Threshold	0/54 (0%)

Note: Number of patients with a threshold value at any post-baseline visit among patients with a non-threshold baseline and at least one post-baseline lab assessment.

Table 8.39
Summary of Threshold Laboratory Values at Any Time Post-Baseline

	Duodart (N=59)
Blood Chemistry	
Alanine Aminotransferase (IU/L)	
>3.0 X ULN	1/56 (2%)
Aspartate Aminotransferase (IU/L)	
>3.0 X ULN	1/56 (2%)
Creatinine (umol/L)	
<0.5 X LLN	0/56 (0%)
>3.0 X ULN	0/56 (0%)
Either Threshold	0/56 (0%)
Glucose (mmol/L)	
<0.7 X LLN	0/56 (0%)
>1.75 X ULN	0/56 (0%)
Either Threshold	0/56 (0%)
Potassium (mmol/L)	
<0.75 X LLN	0/54 (0%)
>1.4 X ULN	0/54 (0%)

Note: Number of patients with a threshold value at any post-baseline visit among patients with a non-threshold baseline and at least one post-baseline lab assessment.

Table 8.39
Summary of Threshold Laboratory Values at Any Time Post-Baseline

	Duodart (N=59)
Either Threshold	0/54 (0%)
Protein (g/L)	
<0.8 X LLN	0/56 (0%)
>1.15 X ULN	0/56 (0%)
Either Threshold	0/56 (0%)
Sodium (mmol/L)	
<0.9 X LLN	0/54 (0%)
>1.15 X ULN	0/54 (0%)
Either Threshold	0/54 (0%)
Urea (mmol/L)	
<0.5 X LLN	0/56 (0%)
>2.0 X ULN	0/56 (0%)
Either Threshold	0/56 (0%)

Note: Number of patients with a threshold value at any post-baseline visit among patients with a non-threshold baseline and at least one post-baseline lab assessment.

Table 8.40
Summary of Baseline Total PSA Values (ug/L)

	Duodart (N=59)
PSA at Baseline	
n	59
Mean	3.474
SD	1.6611
Median	3.010
Min.	1.50
Max.	7.92
PSA at Baseline for patients with PSA at Visit 3 (Month 3)	
n	54
Mean	3.431
SD	1.7021
Median	2.995
Min.	1.50
Max.	7.92
PSA at Baseline for patients with PSA at Visit 5 (Month 6)	
n	52
Mean	3.495
SD	1.7013
Median	3.040
Min.	1.53
Max.	7.92

Note: Baseline is defined as the value on Screening.

Table 8.41
Summary of Total PSA Values (ug/L) at Post-Baseline Visits (LOCF)

PSA At:		Duodart (N=59)
Visit 3 (Month 3)	n	54
	Mean	1.932
	SD	1.2325
	Median	1.580
	Min.	0.35
	Max.	5.91
Visit 5 (Month 6)	n	54
	Mean	1.661
	SD	1.0041
	Median	1.450
	Min.	0.28
	Max.	4.29

Table 8.42
Summary of Total PSA Values (ug/L) at Post-Baseline Visits (At Visit)

PSA At:		Duodart (N=59)
Visit 3 (Month 3)	n	54
	Mean	1.932
	SD	1.2325
	Median	1.580
	Min.	0.35
	Max.	5.91
Visit 5 (Month 6)	n	52
	Mean	1.671
	SD	1.0066
	Median	1.450
	Min.	0.28
	Max.	4.29

Table 8.43
Summary of Total PSA (ug/L) Change from Baseline (LOCF)

PSA Change from Baseline At:		Duodart (N=59)
Visit 3 (Month 3)	n	54
	Mean	-1.499
	SD	1.2263
	Median	-1.270
	Min.	-4.88
	Max.	1.07
Visit 5 (Month 6)	n	54
	Mean	-1.770
	SD	1.2554
	Median	-1.550
	Min.	-5.37
	Max.	0.46

Note: Change from baseline is post-baseline value minus baseline value.

Table 8.44
Summary of Total PSA (ug/L) Change from Baseline (At visit)

PSA Change from Baseline At:		Duodart (N=59)
Visit 3 (Month 3)	n	54
	Mean	-1.499
	SD	1.2263
	Median	-1.270
	Min.	-4.88
	Max.	1.07
Visit 5 (Month 6)	n	52
	Mean	-1.824
	SD	1.2413
	Median	-1.600
	Min.	-5.37
	Max.	0.46

Note: Change from baseline is post-baseline value minus baseline value.

Table 8.45
Summary of Total PSA Percent Change from Baseline (LOCF)

PSA Percent Change from Baseline At:		Duodart (N=59)
Visit 3 (Month 3)	n	54
	Mean	-42.530
	SD	25.0432
	Median	-45.721
	Min.	-84.65
	Max.	39.25
Visit 5 (Month 6)	n	54
	Mean	-49.668
	SD	25.2465
	Median	-55.769
	Min.	-87.89
	Max.	24.46

Note: Percent change from baseline = 100* (post-baseline - baseline value) / baseline value.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_45.sas 27MAY2015 04:59

Table 8.46
Summary of Total PSA Percent Change from Baseline (At visit)

PSA Percent Change from Baseline At:		Duodart (N=59)
Visit 3 (Month 3)	n	54
	Mean	-42.530
	SD	25.0432
	Median	-45.721
	Min.	-84.65
	Max.	39.25
Visit 5 (Month 6)	n	52
	Mean	-50.563
	SD	24.0159
	Median	-55.769
	Min.	-87.89
	Max.	24.46

Note: Percent change from baseline = 100* (post-baseline - baseline value) / baseline value

Table 8.47
Summary of Baseline and at Any Time Post-Baseline Threshold Total PSA Values

	Duodart (N=59)
Baseline Threshold Total PSA [1]	
>2.5 X ULN	0/59 (0%)
At Any time Post Baseline [2]	
>2.5 X ULN	0/54 (0%)

[1] Number of patients with a threshold value at baseline among patients at baseline.
[2] Number of patients with a threshold value at any post-baseline visit among patients with a non-threshold baseline and at least one post-baseline lab.

Table 8.48
Summary of Urinalysis

Treatment: Duodart(N=59)

Urine Test	Planned Relative Time	Positive	Negative
Erythrocytes	Screening	4 (7%)	55 (93%)
	Visit 3 (Month 3)	6 (10%)	48 (81%)
	Visit 5 (Month 6)	6 (10%)	46 (78%)
	Final Value	7 (12%)	47 (80%)
Glucose	Screening	3 (5%)	56 (95%)
	Visit 3 (Month 3)	1 (2%)	53 (90%)
	Visit 5 (Month 6)	0	52 (88%)
	Final Value	0	54 (92%)
Ketones	Screening	0	59 (100%)
	Visit 3 (Month 3)	2 (3%)	52 (88%)
	Visit 5 (Month 6)	1 (2%)	51 (86%)
	Final Value	1 (2%)	53 (90%)
Leukocytes	Screening	3 (5%)	56 (95%)
	Visit 3 (Month 3)	0	54 (92%)
	Visit 5 (Month 6)	6 (10%)	46 (78%)
	Final Value	6 (10%)	48 (81%)

Note: Change from baseline is post-baseline value minus baseline value.
Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.48
Summary of Urinalysis

Treatment: Duodart(N=59)

Urine Test	Planned Relative Time	Positive	Negative
Protein	Screening	9 (15%)	50 (85%)
	Visit 3 (Month 3)	6 (10%)	48 (81%)
	Visit 5 (Month 6)	7 (12%)	45 (76%)
	Final Value	8 (14%)	46 (78%)

Note: Change from baseline is post-baseline value minus baseline value.
Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.49
Summary of ECG

	Duodart (N=59)
Screening	
Normal	10/59 (17%)
Abnormal	49/59 (83%)
Visit 1 (Month 1)	
Normal	9/56 (16%)
Abnormal	47/56 (84%)
Visit 3 (Month 3)	
Normal	3/53 (6%)
Abnormal	50/53 (94%)
Visit 5 (Month 6)	
Normal	8/52 (15%)
Abnormal	44/52 (85%)

Table 8.50
Summary of Digital Rectal Examination

	Duodart (N=59)
Screening	
Normal	1/59 (2%)
Abnormal	58/59 (98%)
Visit 5 (Month 6)	
Normal	3/52 (6%)
Abnormal	49/52 (94%)
Any Change from Normal at Baseline to Abnormal at Post-Baseline Visit 5 (Month 6)	0/52 (0%)

Note: Baseline is defined as the value obtained at screening.

Table 8.51
Summary of Vital Signs

Treatment: Duodart(N=59)

Vital Parameter (Unit)	Visit	n	Mean	SD	Median	Min.	Max.
Systolic Blood Pressure (mmHg)	Screening	59	124.7	13.56	120.0	100	160
	Visit 1 (Month 1)	56	120.7	13.60	120.0	100	180
	Visit 2 (Month 2)	55	121.6	14.63	120.0	100	180
	Visit 3 (Month 3)	54	122.8	11.06	120.0	90	160
	Visit 4 (Month 4.5)	52	122.3	11.13	120.0	100	160
	Visit 5 (Month 6)	52	121.2	8.08	120.0	110	140
	Final Value	56	121.6	8.26	120.0	110	140
Diastolic Blood Pressure (mmHg)	Screening	59	72.2	7.21	70.0	60	90
	Visit 1 (Month 1)	56	70.8	8.33	70.0	60	90
	Visit 2 (Month 2)	55	70.5	8.03	70.0	60	90
	Visit 3 (Month 3)	54	72.0	7.37	70.0	60	90
	Visit 4 (Month 4.5)	52	72.3	8.07	70.0	60	90
	Visit 5 (Month 6)	52	73.3	6.48	70.0	60	90
	Final Value	56	73.0	6.58	70.0	60	90

Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.51
Summary of Vital Signs

Treatment: Duodart(N=59)

Vital Parameter (Unit)	Visit	n	Mean	SD	Median	Min.	Max.
Heart Rate (Beats/Min)	Screening	59	82.4	7.11	82.0	64	102
	Visit 1 (Month 1)	56	81.8	6.59	83.0	62	94
	Visit 2 (Month 2)	55	82.2	7.78	82.0	62	110
	Visit 3 (Month 3)	54	80.4	7.52	80.0	62	102
	Visit 4 (Month 4.5)	52	82.5	5.24	84.0	66	98
	Visit 5 (Month 6)	52	80.7	4.69	80.0	67	90
	Final Value	56	80.7	4.56	80.0	67	90
Respiratory Rate (Breaths/Min)	Screening	59	18.6	1.58	19.0	16	20
	Visit 1 (Month 1)	56	18.8	1.55	20.0	16	20
	Visit 2 (Month 2)	55	19.1	1.17	20.0	16	20
	Visit 3 (Month 3)	54	19.2	1.26	20.0	16	20
	Visit 4 (Month 4.5)	52	19.5	0.96	20.0	16	20
	Visit 5 (Month 6)	52	19.7	0.69	20.0	18	20
	Final Value	56	19.7	0.67	20.0	18	20

Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.51
Summary of Vital Signs

Treatment: Duodart(N=59)

Vital Parameter (Unit)	Visit	n	Mean	SD	Median	Min.	Max.
Temperature (^{o}C)	Screening	59	36.99	0.194	37.00	36.5	37.6
	Visit 1 (Month 1)	56	36.87	0.238	37.00	36.5	37.5
	Visit 2 (Month 2)	55	36.89	0.180	37.00	36.5	37.1
	Visit 3 (Month 3)	54	36.89	0.195	37.00	36.2	37.2
	Visit 4 (Month 4.5)	52	36.96	0.116	37.00	36.5	37.1
	Visit 5 (Month 6)	52	36.97	0.122	37.00	36.7	37.5
	Final Value	56	36.97	0.123	37.00	36.7	37.5

Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.52
Summary of Vital Signs Change from Baseline

Treatment: Duodart(N=59)

Vital Parameter (Unit)	Visit	n	Mean	SD	Median	Min.	Max.
Systolic Blood Pressure (mmHg)	Visit 1 (Month 1)	56	-3.6	13.54	0.0	-50	30
	Visit 2 (Month 2)	55	-2.7	13.12	0.0	-50	20
	Visit 3 (Month 3)	54	-1.1	12.98	0.0	-40	30
	Visit 4 (Month 4.5)	52	-1.7	12.00	0.0	-40	20
	Visit 5 (Month 6)	52	-2.9	11.94	0.0	-40	20
	Final Value	56	-2.7	11.68	0.0	-40	20
Diastolic Blood Pressure (mmHg)	Visit 1 (Month 1)	56	-1.2	9.40	0.0	-30	20
	Visit 2 (Month 2)	55	-1.5	9.51	0.0	-20	20
	Visit 3 (Month 3)	54	0.2	9.42	0.0	-20	20
	Visit 4 (Month 4.5)	52	0.4	10.66	0.0	-30	30
	Visit 5 (Month 6)	52	1.3	10.48	0.0	-20	20
	Final Value	56	1.1	10.39	0.0	-20	20

Change from baseline is post-baseline value minus baseline value.
Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_52.sas 27MAY2015 04:59

Table 8.52
Summary of Vital Signs Change from Baseline

Treatment: Duodart(N=59)

Vital Parameter (Unit)	Visit	n	Mean	SD	Median	Min.	Max.
Heart Rate (Beats/Min)	Visit 1 (Month 1)	56	-0.9	7.78	0.0	-18	16
	Visit 2 (Month 2)	55	-0.4	8.52	1.0	-28	19
	Visit 3 (Month 3)	54	-2.3	9.18	-2.0	-24	18
	Visit 4 (Month 4.5)	52	-0.2	8.24	2.0	-18	18
	Visit 5 (Month 6)	52	-2.0	9.05	-2.0	-24	22
	Final Value	56	-1.9	8.79	-2.0	-24	22
Respiratory Rate (Breaths/Min)	Visit 1 (Month 1)	56	0.2	1.96	0.0	-4	4
	Visit 2 (Month 2)	55	0.5	1.81	0.0	-4	4
	Visit 3 (Month 3)	54	0.6	2.03	0.0	-2	4
	Visit 4 (Month 4.5)	52	0.8	1.85	0.0	-4	4
	Visit 5 (Month 6)	52	1.1	1.64	0.0	-2	4
	Final Value	56	1.1	1.64	0.0	-2	4

Change from baseline is post-baseline value minus baseline value.
Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.

Table 8.52
Summary of Vital Signs Change from Baseline

Treatment: Duodart(N=59)

Vital Parameter (Unit)	Visit	n	Mean	SD	Median	Min.	Max.
Temperature (^{o}C)	Visit 1 (Month 1)	56	-0.13	0.316	0.00	-1.1	0.5
	Visit 2 (Month 2)	55	-0.11	0.276	0.00	-1.0	0.6
	Visit 3 (Month 3)	54	-0.11	0.283	0.00	-1.0	0.4
	Visit 4 (Month 4.5)	52	-0.04	0.226	0.00	-0.6	0.5
	Visit 5 (Month 6)	52	-0.03	0.217	0.00	-0.6	0.5
	Final Value	56	-0.03	0.213	0.00	-0.6	0.5

Change from baseline is post-baseline value minus baseline value.
Note: The Final Value of a parameter for each patient is defined as the latest post-baseline value available in the study for that patient.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_8_52.sas 27MAY2015 04:59

Table 8.53
Summary of Vital Signs Exceeding Threshold at Baseline

	Duodart (N=59)
Any Threshold Value	2/56 (4%)
Systolic Blood Pressure	
<80 mmHg	0/56 (0%)
>165 mmHg	0/56 (0%)
Either Threshold	0/56 (0%)
Diastolic Blood Pressure	
<40 mmHg	0/56 (0%)
>105 mmHg	0/56 (0%)
Either Threshold	0/56 (0%)
Heart Rate	
<40 beats per minute	0/56 (0%)
>100 beats per minute	2/56 (4%)
Either Threshold	2/56 (4%)

Note: Only patients with a baseline value and at least one post-baseline value are included in this display.

Table 8.54
Summary of Vital Signs Exceeding Threshold at Any Post-Baseline Visit

	Duodart (N=59)
Any Threshold Value	3/56 (5%)
Systolic Blood Pressure	
<80 mmHg	0/56 (0%)
>165 mmHg	1/56 (2%)
Either Threshold	1/56 (2%)
Diastolic Blood Pressure	
<40 mmHg	0/56 (0%)
>105 mmHg	0/56 (0%)
Either Threshold	0/56 (0%)
Heart Rate	
<40 beats per minute	0/56 (0%)
>100 beats per minute	2/56 (4%)
Either Threshold	2/56 (4%)

Note: Only patients with a baseline value and at least one post-baseline value are included in this display.

Table 8.55
Summary of Transrectal Prostate Ultrasonography (TRUS)

	Duodart (N=59)
Screening	
Normal	0/59 (0%)
Abnormal	59/59 (100%)
Visit 5 (Month 6)	
Normal	0/52 (0%)
Abnormal	52/52 (100%)

Table 9.1
Summary of SFI Imputations

	Duodart (N=59)
Number of patients with at least one administered questionnaire	59
Number (%) of patients with at least one imputation	0
Number of questionnaires (across patients and visits)	165
Number (%) of questionnaires not requiring an imputation [1]	165 (100%)

Note: [1] All 3 questions answered.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_9_1.sas 27MAY2015 05:00

Table 9.2
Summary of SFI At Baseline

	Duodart (N=59)
n	59
Mean	7.6
SD	3.23
Median	8.0
Min.	0
Max.	12

Note: Baseline is defined as the value obtained at Screening.

Table 9.3
Summary of SFI at Each Post-Baseline Visit (LOCF)

SFI At:	Duodart (N=59)
Visit 3 (Month 3)	
n	54
Mean	8.2
SD	3.47
Median	9.0
Min.	0
Max.	12
Visit 5 (Month 6)	
n	54
Mean	8.5
SD	3.47
Median	9.5
Min.	0
Max.	12

Table 9.4
Summary of SFI at Each Post-Baseline Visit (At Visit)

SFI At:	Duodart (N=59)
Visit 3 (Month 3)	
n	54
Mean	8.2
SD	3.47
Median	9.0
Min.	0
Max.	12
Visit 5 (Month 6)	
n	52
Mean	8.4
SD	3.53
Median	9.5
Min.	0
Max.	12

Table 9.5
Summary of SFI Change from Baseline (LOCF)

SFI Change from Baseline At:	Duodart (N=59)
Visit 3 (Month 3)	
n	54
Mean	0.6
SD	2.42
Median	0.0
Min.	-7
Max.	6
Visit 5 (Month 6)	
n	54
Mean	0.9
SD	2.65
Median	0.0
Min.	-8
Max.	6

Note: Change from baseline is post-baseline value minus baseline value.

Table 9.6
Summary of SFI Change from Baseline (At Visit)

SFI Change from Baseline At:	Duodart (N=59)
Visit 3 (Month 3)	
n	54
Mean	0.6
SD	2.42
Median	0.0
Min.	-7
Max.	6
Visit 5 (Month 6)	
n	52
Mean	0.8
SD	2.68
Median	0.0
Min.	-8
Max.	6

Note: Change from baseline is post-baseline value minus baseline value.

Table 9.7
Summary of SFI Percent Change from Baseline (LOCF)

SFI Percent Change from Baseline At:	Duodart (N=59)
Visit 3 (Month 3)	
n	52
Mean	8.3
SD	39.27
Median	0.0
Min.	-100
Max.	120
Visit 5 (Month 6)	
n	52
Mean	17.7
SD	42.01
Median	0.0
Min.	-100
Max.	125

Note: Percent change from baseline = 100*(post-baseline - baseline value)/baseline value.

Table 9.8
Summary of SFI Percent Change from Baseline (At Visit)

SFI Percent Change from Baseline At:	Duodart (N=59)
Visit 3 (Month 3)	
n	52
Mean	8.3
SD	39.27
Median	0.0
Min.	-100
Max.	120
Visit 5 (Month 6)	
n	50
Mean	16.9
SD	42.59
Median	0.0
Min.	-100
Max.	125

Note: Percent change from baseline = 100*(post-baseline - baseline value)/baseline value.
/sasdata/pb3513207/Urology/DUODART/FDC114785/final/dev/output/t_9_8.sas 27MAY2015 05:00