

Compilation of Spontaneous Neoplastic Lesions and Survival in Crl:CD[®](SD) Rats from Control Groups

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INTRODUCTION:

In the course of data analysis from a carcinogenicity study, statistical tests will occasionally indicate that the incidence of a particular neoplasm is significantly greater in a treated group than in the concurrent control. Since statistical differences can occur as a matter of chance alone, using a positive statistical difference as the sole or definitive evaluation tool could produce a false positive result (6,10). Alternatively, a slight increase in the incidence of a rare neoplasm would be unlikely to achieve statistical significance by the tests typically employed in toxicology studies. In this type of situation, the use of historical control data could justify the biological significance of even a slight increase in the incidence of an uncommon neoplasm (10).

The histopathology and survival data presented in this publication were gathered from thirty-one toxicology studies of approximately 104 weeks duration. All studies were conducted in accordance with Good Laboratory Practice regulations of the US Food and Drug Administration or the Environmental Protection Agency and/or the Standard Operating Procedures of the participating laboratory. All studies were performed in the United States, Europe, Canada or Japan by contract laboratories, academic institutions or industrial toxicology facilities. All studies were conducted in support of in-house research or marketing permits. The data presented were provided to us by the individual laboratories or gathered from the published literature by means of a comprehensive literature search. The search tools used included Dialog Web, an internet-based search tool published by Dialog Corp, a Thompson company; Nexis.com, a component of the internet based Lexis-Nexis services; and PubMed (3,4,13).

PURPOSE:

The purpose of this compilation is to offer the study director, reviewing toxicologist and/or study pathologist some reported incidences of neoplasms and survival data in CrI:CD[®](SD) rats maintained as control animals throughout their lifetime, typically 104 weeks. This document was prepared for informational purposes only. Diagnoses of the various neoplasms in the compilations are intentionally grouped in a manner to provide the user with a range of reported incidences of similar types of lesions. This compilation is not intended in any way to propose a system of standardized nomenclature nor does it separately include each and every reported variant of each lesion. For these reasons, care should be taken in using these data that are not intended as a substitute for historical data collected within an institution.

COMMON STUDY PARAMETERS:

The 31 studies included in this publication were initiated or published between 1989 and 2002 at eight different industrial or contract testing facilities in the United States, Europe, Canada and Japan. All studies used CrI:CD[®](SD) rats from Charles River Laboratories. Rats in studies 15-19 and 25-31 were confirmed to be from CrI:CD[®](SD) colonies produced under the IGS system. The International Genetic Standard (IGS) is a breeding system that CRL implemented in the mid-1990's to stabilize the degree of genetic diversity represented among colonies of CrI:CD[®](SD) rats, both horizontally (among colonies worldwide) and longitudinally (over subsequent generations). Rats from other studies were not reported as having originated from IGS colonies, although it is possible that some were, in fact, being operated using the IGS system. CRL has never received any information to indicate that CrI:CD[®](SD) rats have a different tumor profile in the IGS system. Additional information regarding the IGS system and on background data for CrI:CD[®](SD) IGS rats is available (14-16).

The rats in these studies were from control groups of dietary, gavage, or subcutaneous dosing studies and were approximately 4-8 weeks of age at study initiation. Dietary study control groups received untreated diet while groups from oral dosing studies received 1.0% polyethylene glycol; 0.5% aqueous methylcellulose; 1.0% aqueous carboxymethylcellulose; or deionized water as the vehicle control. The animals from the subcutaneous dosing study received sterile water for injection (USP) and some groups were untreated.

Rats included in this publication were singly housed in stainless steel wire mesh cages with free access to water. The animal rooms were generally maintained at average temperatures of 72 +/- 5 degrees Fahrenheit with an average relative humidity of 30-70%. A 12hr/12hr light/dark cycle was employed in all

studies. Since these studies were conducted in different facilities, there was some variation in environmental conditions. However, the overall environmental conditions were not considered by those performing the studies to have had any effect on the quality or integrity of the studies. Rats were allowed free access to tap water and one of the following commercial diets; Purina PMI Certified Rodent Chow 5002, CR-LPF (Oriental Yeast Co., Ltd., Japan), CRF-1 (Oriental Yeast Co., Ltd., Japan) or Corticella diet (Laboratorio Dottori Piccioni).

DATA SETS REPRESENTED:

Survival data are presented by study as the actual number surviving to terminal sacrifice and as percent survival at terminal sacrifice (Tables 1 and 2). The survival data are also presented in graphic form (Graphs 1 and 2). The designation N/A indicates that the survival data was not available to us at the time of publication or in the case of study 24 that the animals were maintained until death and no terminal sacrifice was performed.

The overall incidences of all neoplastic lesions observed in any organ are reported and are summarized in Tables 3 and 4. These data also include neoplastic lesions from rats that died or were found moribund and killed prior to terminal sacrifice, but not from rats that were killed for an interim sacrifice. Due to the apparent diversity in terminology and the variability among studies in the incidence of particular lesions, the individual study incidences of lesions in selected organs/systems are also presented (Tables 5 and 6). These organs/systems include liver, pituitary, thyroid, adrenal, pancreas, mammary gland, and whole body/multiple organ.

SUMMARY TABLE CALCULATIONS FOR NEOPLASTIC LESIONS:

The following is a description of how each of the parameters in the tables was calculated.

Number of Studies (# Studies)

This is the number of studies in which a particular tissue/organ was examined. In this presentation, the number of studies is 30 for males and 31 for females.

Total Number of Organs (Total # Organs)

This number represents the sum of the total number of tissues or organs examined in all control groups from all studies combined. Widespread tumors that showed involvement of multiple organs were listed on the basis of total number of animals examined. Occasionally a tumor would be noticed in a tissue not designated for histological examination by the study protocol. In these instances, the tumor incidence was based on the total number of animals examined as any such tumor or lesion would have been noticed on gross examination of the animal. Autolysis of tissues did not routinely exclude tissues from diagnosis. Some laboratories presented data separately for different regions within an organ (i.e., duodenum, jejunum and ileum) while most presented data by the organ (i.e., small intestine). When data were presented separately by organ region, they were grouped under the organ and calculations were based on the number of organs examined.

Total Number of Lesions (# Lesions)

This represents the total number of occurrences of this lesion in the specified organ in all studies examined.

Percent of Total

These values represent the percent incidence of a particular lesion/diagnosis in the total number (all studies combined) of a particular organ examined. These values were calculated by dividing the total number of lesions by the total number of organs/animals examined and multiplying by 100 to express the values as a percent. Values are expressed to the second decimal place. Some caution is indicated in using this number, since not all pathologists or institutions will include all diagnoses in their lexicon.

Number of Studies Using This Diagnosis

This is the number of studies in which a particular diagnosis was reported. This number may be useful in interpreting the overall incidence (percent of total) of a particular diagnosis, see above.

Minimum and Maximum Percent Found (Minimum and Maximum % Found)

The range reported is the lowest and highest percent incidence for each lesion from the studies where the diagnosis was made. Therefore, if a study did not include a particular diagnosis, it was excluded from these calculations. The minimum and maximum percent found values should be considered in conjunction with the Number of Studies Using the Diagnosis.

The individual study percentages, Minimum % Found and Maximum % Found, were calculated by dividing the number of times each diagnosis was made by the total number of organs examined in each study and then multiplying the resultant value by 100 to express it as a percent. Values are expressed to the second decimal place.

SYNONYMS FOR NEOPLASTIC LESIONS:

Synonymous terms or diagnoses were frequently encountered in different studies, and were combined under a single, often broad diagnosis, which was considered to be the primary diagnosis, shown below in CAPITAL LETTERS. Although some effort was made to use currently acceptable terms, it is beyond the scope of this publication to propose a system of preferred diagnoses. A current trend in toxicologic pathology is to simplify tumor classification (i.e., “lumping” as opposed to “splitting”) and the categories of neoplasms used in this publication are considered to be consistent with that trend. The synonyms which were included in the various diagnoses are presented in the synonym list which follows. Where possible, terminology is consistent with the classification system proposed by the Society of Toxicologic Pathologists.

Stomach:

NONGLANDULAR MUCOSA/SQUAMOUS CELL PAPILOMA = papilloma; non-glandular mucosa papilloma; squamous cell papilloma
NONGLANDULAR MUCOSA, CARCINOMA = squamous cell carcinoma

Liver:

BILE DUCT ADENOMA = cholangioma

Lung:

ADENOMA/ALVEOLAR/BRONCHIOLAR = papilloma

Uterus:

ENDOMETRIAL STROMAL POLYP = polyp
ENDOMETRIUM, ADENOCARCINOMA = adenocarcinoma; endometrium, carcinoma
ENDOMETRIAL STROMAL SARCOMA = sarcoma

Skin:

BASAL CELL CARCINOMA = malignant basal cell tumor

Mammary Gland:

ADENOMA = cystadenoma

Adrenal:

CORTEX, CARCINOMA= cortex, adenocarcinoma
PHEOCHROMOCYTOMA, BENIGN= medulla neoplasm, benign
PHEOCHROMOCYTOMA, MALIGNANT= medulla neoplasm, malignant

Pancreas:

ISLET CELL, ADENOMA= islet, adenoma; adenoma, not otherwise specified
ISLET CELL, CARCINOMA = islet cell, adenocarcinoma; islet, carcinoma

Pituitary:

ADENOMA = adenoma anterior lobe; adenoma pars distalis; acidophil adenoma; basophil adenoma; chromophobe adenoma
CARCINOMA = carcinoma pars distalis; adenocarcinoma; adenocarcinoma pars distalis; chromophobe carcinoma

Skin:

MALIGNANT SCHWANNOMA = neurofibrosarcoma
TRICHOEPITHELIOMA = trichofolliculoma

Thyroid:

C-CELL = parafollicular cell
FOLLICULAR CELL CARCINOMA = follicular cell adenocarcinoma

Urinary Bladder:

UROTHELIAL CARCINOMA = transitional cell carcinoma

Body:

WHOLE BODY/MULTIPLE ORGAN = primary site undetermined
LYMPHOMA, LYMPHOCYTIC = lymphoma, malignant; leukemia, lymphocytic
LYMPHOMA/LEUKEMIA COMBINED = This designation applies only to study 24 in which the incidence of these neoplasms was reported as combined only.

ABBREVIATIONS:

NA = Not Available

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Table 1: Summary of Individual Study Information and Survival/Males

Study Identification/Publication	1	2	3	4	5	6	7	8	9	10
Study Initiation/Publication Date	1994-96	1994-96	1992	1994	1996	1992	1992	1993	1992	1994
Total Number on Study	130	115	60	110	54	50	52	50	60	70
Number Surviving to Termination	56	45	25	25	13	10	13	17	20	12
% Survival	43.1	39.1	41.7	22.7	24.1	20.0	25.0	34.0	33.3	17.1
Study Duration in Weeks	104	104	104	104	104	104	104	104	104	104

Study Identification/Publication	11	12	13	14	15	16	17	18	19	20
Study Initiation/Publication Date	1996	1996	1995	1995	1996	1996	1996	1996	1997	1997
Total Number on Study	70	70	70	60	50	50	50	50	60	70
Number Surviving to Termination	31	36	19	20	25	26	18	16	30	44
% Survival	44.3	51.4	27.1	33.3	50.0	52.0	36.0	32.0	50.0	62.9
Study Duration in Weeks	104	104	104	104	104	104	104	104	104	104

Study Identification/Publication	21	22	23	24	25	26	27	28	29	30
Study Initiation/Publication Date	1997	1997	1991	2002	1999	2000	1997	1999	1998	1998
Total Number on Study	60	60	60	75	90	180	60	70	70	70
Number Surviving to Termination	31	22	19	NA	50	NA	21	29	41	29
% Survival	51.7	36.7	31.7		55.6		35.0	41.4	58.6	41.4
Study Duration in Weeks	104	104	104	>104	104	98-104	103	104	101	101

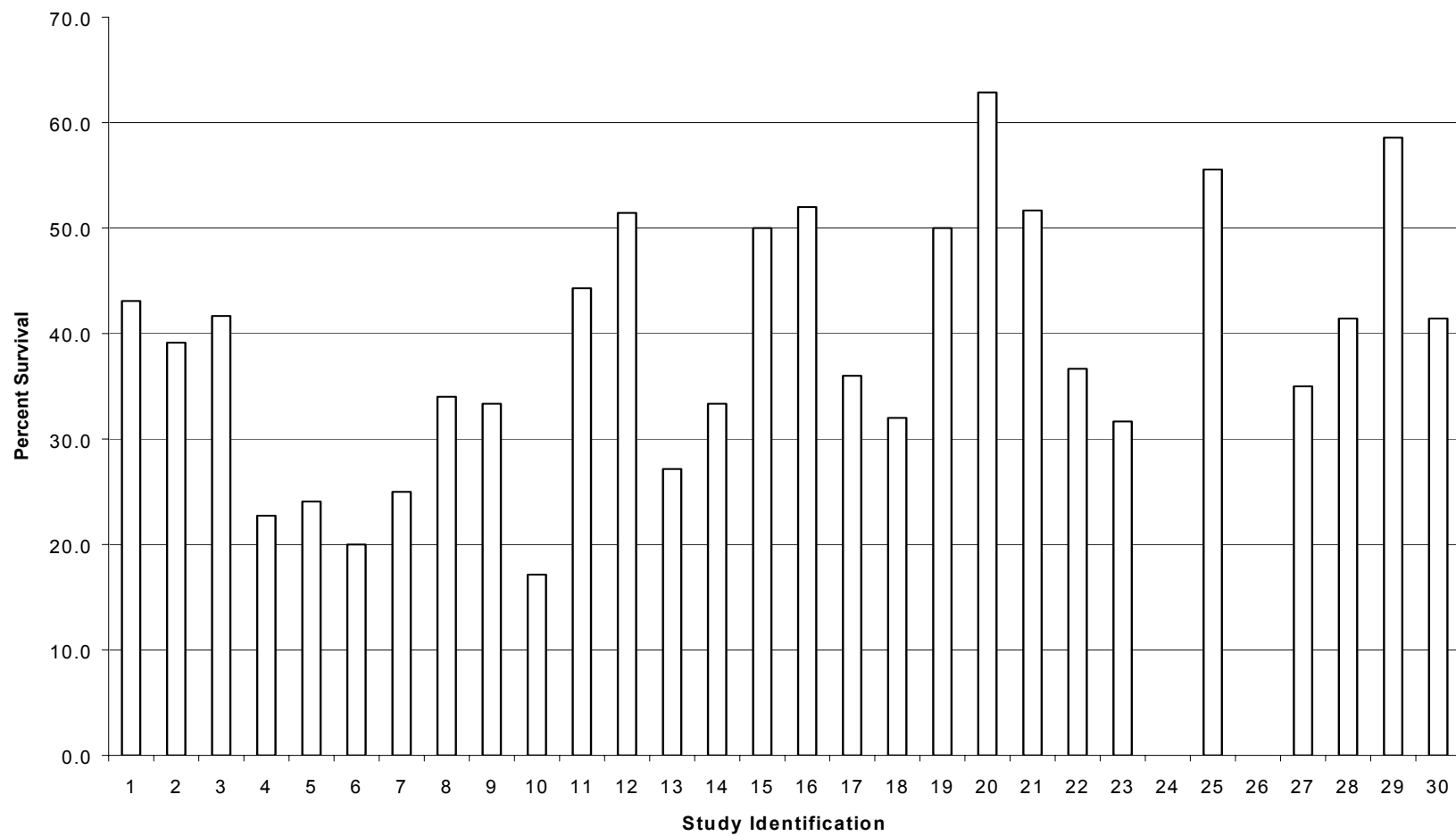
Table 2: Summary of Individual Study Information and Survival/Females

Study Identification/Publication	1	2	3	4	5	6	7	8	9	10	11
Study Initiation/Publication Date	1994-96	1994-96	1992	1994	1996	1992	1992	1993	1992	1994	1996
Total Number on Study	130	115	60	110	54	50	51	49	60	70	70
Number Surviving to Termination	44	41	27	41	13	15	15	24	20	14	20
% Survival	33.8	35.7	45.0	37.3	24.1	30.0	29.4	49.0	33.3	20.0	28.6
Study Duration in Weeks	104	104	104	104	104	104	104	104	104	104	104

Study Identification/Publication	12	13	14	15	16	17	18	19	20	21
Study Initiation/Publication Date	1996	1995	1995	1996	1996	1996	1996	1997	1997	1997
Total Number on Study	70	70	60	50	50	50	50	60	70	60
Number Surviving to Termination	24	21	17	25	24	19	17	29	43	21
% Survival	34.3	30.0	28.3	50.0	48.0	38.0	34.0	48.3	61.4	35.0
Study Duration in Weeks	104	104	104	104	104	104	104	104	104	104

Study Identification/Publication	22	23	24	25	26	27	28	29	30	31
Study Initiation/Publication Date	1997	1991	2002	1999	2000	1997	1999	1998	1998	1994-96
Total Number on Study	60	60	75	90	180	60	70	70	70	200
Number Surviving to Termination	19	27	NA	56	NA	17	28	16	19	68
% Survival	31.7	45.0		62.2		28.3	40.0	22.9	27.1	34.0
Study Duration in Weeks	104	104	>104	104	98-104	103	104	101	101	104

Graph 1: Male Survival-104 Weeks



Graph 2: Female Survival-104 Weeks

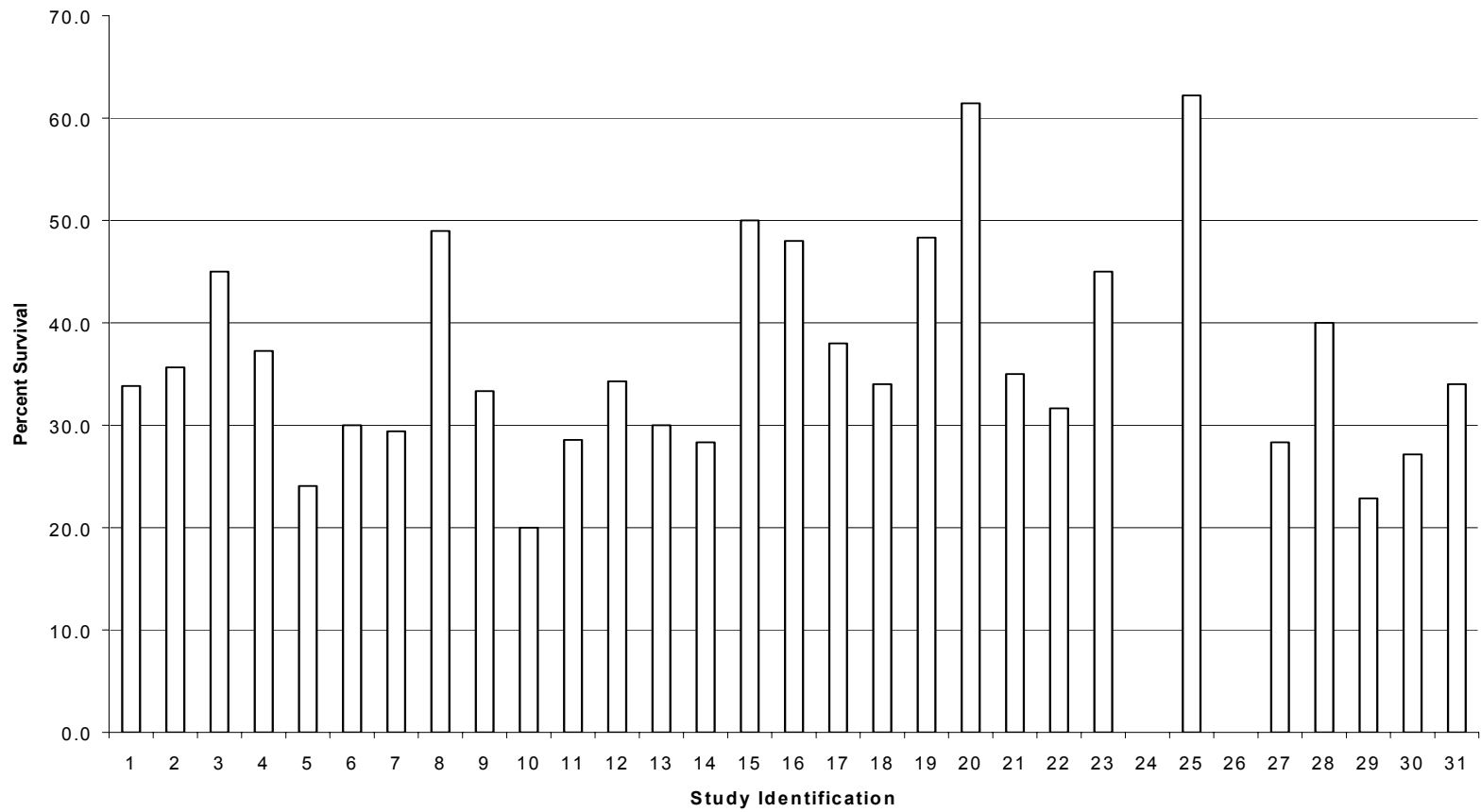


Table 3: Neoplasms/Males-104 Weeks

		TOTAL		#STUDIES		
		#ORGANS	PERCENT	USING	MINIMUM	MAXIMUM
LOCATION AND TUMOR	#STUDIES	#LESIONS	OF TOTAL	THIS	% FOUND	% FOUND
				DIAGNOSIS		
ORAL CAVITY/TONGUE/LIPS	30	2146				
Fibrosarcoma		2	0.09	2	0.91	1.33
Keratoacanthoma		1	0.05	1	2.00	2.00
Carcinoma		2	0.09	1	2.67	2.67
SALIVARY GLAND	30	2145				
Adenoma		1	0.05	1	1.43	1.43
Mesothelioma		1	0.05	1	1.67	1.67
Schwannoma, Benign		1	0.05	1	1.43	1.43
ESOPHAGUS	30	2146				
Anaplastic Carcinoma		1	0.05	1	0.87	0.87
STOMACH	30	2146				
Adenocarcinoma		2	0.09	2	1.43	2.00
Acanthoma		5	0.23	1	6.67	6.67
SMALL INTESTINE	30	2146				
Adenocarcinoma		5	0.23	5	1.11	2.00
Leiomyoma		1	0.05	1	1.43	1.43
Leiomyosarcoma		1	0.05	1	1.43	1.43
LARGE INTESTINE/CECUM/ANUS	30	2145				
Adenocarcinoma		1	0.05	1	0.77	0.77
Leiomyoma		1	0.05	1	0.77	0.77
Leiomyosarcoma		2	0.09	2	1.33	1.43
LIVER	30	2146				
Anaplastic Carcinoma		1	0.05	1	0.87	0.87
Hepatocellular Adenoma		43	2.00	20	0.56	8.00
Hepatocellular Carcinoma		48	2.24	20	0.77	6.67
Angiosarcoma		2	0.09	2	1.33	1.43
MESENTERY	30	2146				
Anaplastic Carcinoma		1	0.05	1	0.87	0.87
Fibroma		1	0.05	1	1.43	1.43
Hemangiosarcoma		2	0.09	2	1.43	2.00
Leiomyosarcoma		1	0.05	1	1.43	1.43

		TOTAL		#STUDIES		
		#ORGANS	PERCENT	USING THIS	MINIMUM	MAXIMUM
LOCATION AND TUMOR	#STUDIES	#LESIONS	OF TOTAL	DIAGNOSIS	% FOUND	% FOUND
Lipoma		3	0.14	2	0.87	2.22
Liposarcoma		1	0.05	1	1.92	1.92
Mesothelioma, Malignant		3	0.14	3	0.77	1.43
NASAL CAVITY	30	2146				
Schwannoma, Malignant		1	0.05	1	2.00	2.00
LUNG	30	2146				
Adenoma, Alveolar/Bronchiolar		3	0.14	3	1.43	2.00
Adenocarcinoma, Alveolar/Bronchiolar		2	0.09	2	1.43	2.00
KIDNEY	30	2146				
Adenoma/Tubular Adenoma		9	0.42	7	1.33	4.00
Adenocarcinoma/Tubular Adenocarcinoma		8	0.37	7	1.43	4.00
Lipoma		13	0.61	13	1.11	2.00
Liposarcoma		4	0.19	4	0.56	2.00
Mesenchymal Tumor, Malignant		6	0.28	4	0.77	1.85
Nephroblastoma, Malignant		1	0.05	1	1.43	1.43
Transitional Cell Carcinoma		1	0.05	1	1.67	1.67
URINARY BLADDER	30	2145				
Anaplastic Carcinoma		1	0.05	1	0.87	0.87
Urothelial Papilloma		4	0.19	3	1.43	3.33
Urothelial Carcinoma		2	0.09	2	1.67	2.00
TESTIS	30	2145				
Interstitial Cell Tumor, Benign		52	2.42	18	1.11	9.33
Interstitial Cell Tumor, Malignant		5	0.23	3	1.67	3.33
Mesothelioma, Malignant		1	0.05	1	1.43	1.43
SEMINAL VESICLE	30	2134				
Adenoma		1	0.05	1	1.43	1.43
Adenocarcinoma		1	0.05	1	0.56	0.56
Anaplastic Carcinoma		1	0.05	1	0.87	0.87
PROSTATE	30	2144				
Adenoma		6	0.28	5	1.43	2.00
PREPUTIAL GLAND	30	2146				
Adenoma		1	0.05	1	1.67	1.67
Squamous Cell Carcinoma		2	0.09	2	0.77	1.85

		TOTAL		#STUDIES		
		#ORGANS	PERCENT	USING THIS	MINIMUM	MAXIMUM
LOCATION AND TUMOR	#STUDIES	#LESIONS	OF TOTAL	DIAGNOSIS	% FOUND	% FOUND
EPIDIDYMISS	30	2146				
Leiomyosarcoma		1	0.05	1	1.67	1.67
SKIN/SUBCUTANEOUS TISSUE	30	2146				
Basal Cell Tumor, Benign		11	0.51	8	0.56	4.00
Basal Cell Carcinoma		7	0.33	6	0.77	1.82
Fibroma		86	4.01	26	1.11	10.77
Squamous Cell Carcinoma		11	0.51	8	0.91	4.00
Fibrosarcoma		30	1.40	17	0.87	5.00
Hemangioma		3	0.14	1	5.77	5.77
Hemangiosarcoma		2	0.09	2	1.43	2.00
Keratoacanthoma		52	2.42	20	1.11	10.00
Lipoma		47	2.19	21	0.91	6.96
Liposarcoma		6	0.28	3	1.43	5.33
Lymphangioma		1	0.05	1	0.56	0.56
Myxoma		3	0.14	3	1.67	2.00
Myxosarcoma		2	0.09	2	0.77	1.43
Osteosarcoma		4	0.19	3	1.43	2.86
Pilomatrixoma, Benign		5	0.23	5	0.87	1.85
Rhabdomyosarcoma		2	0.09	2	0.77	1.43
Schwannoma, Malignant		6	0.28	6	0.77	2.00
Sebaceous Gland Adenoma		13	0.61	7	0.56	4.62
Squamous Cell Papilloma		34	1.58	16	0.87	6.00
Trichoepithelioma, Benign		9	0.42	7	1.33	4.29
MAMMARY GLAND	30	2146				
Adenoma		5	0.23	5	0.87	2.00
Adenocarcinoma		12	0.56	8	0.56	4.29
Fibroadenoma/Fibroma		24	1.12	12	1.11	5.77
Fibrosarcoma		1	0.05	1	2.00	2.00
Lipoma		4	0.19	2	2.00	4.00
Liposarcoma		2	0.09	1	2.67	2.67
ADRENAL	30	2144				
Cortex, Adenoma		44	2.05	22	0.91	8.00
Cortex, Carcinoma		11	0.51	11	0.77	2.00
Pheochromocytoma, Benign		233	10.87	28	1.43	24.29
Pheochromocytoma, Malignant		30	1.40	17	1.43	5.00
PANCREAS	30	2142				
Acinar Cell, Adenoma		29	1.35	13	1.12	11.43
Acinar Cell, Carcinoma		8	0.37	7	0.87	3.33
Islet Cell, Adenoma		148	6.91	22	1.67	25.71

		TOTAL		#STUDIES		
		#ORGANS	PERCENT	USING THIS	MINIMUM	MAXIMUM
LOCATION AND TUMOR	#STUDIES	#LESIONS	OF TOTAL	DIAGNOSIS	% FOUND	% FOUND
Islet Cell, Carcinoma		52	2.43	16	0.77	14.00
Mixed Adenoma		1	0.05	1	0.87	0.87
PITUITARY	30	2138				
Adenoma		1002	46.87	30	0.77	70.00
Carcinoma		43	2.01	10	0.77	36.00
Craniopharyngioma		1	0.05	1	1.67	1.67
Ganglioneuroma		1	0.05	1	0.77	0.77
Granular Cell Tumor, Malignant		1	0.05	1	1.43	1.43
THYROID	30	2141				
C-Cell, Adenoma		168	7.85	28	1.43	14.77
C-Cell, Carcinoma		30	1.40	16	0.56	14.81
Follicular Cell, Adenoma		62	2.90	21	1.67	12.00
Follicular Cell, Carcinoma		19	0.89	13	0.87	3.85
PARATHYROID	30	2138				
Adenoma		42	1.96	16	0.77	8.33
BRAIN	30	2146				
Astrocytoma, Malignant		26	1.21	13	0.87	4.29
Ependymoma		1	0.05	1	1.43	1.43
Glioma, Malignant		3	0.14	3	0.91	1.92
Granular Cell Tumor, Benign		8	0.37	8	0.56	2.00
Granular Cell Tumor, Malignant		4	0.19	3	1.43	2.86
Hemangiosarcoma		1	0.05	1	1.92	1.92
Meningeal Sarcoma		1	0.05	1	0.87	0.87
Neuroma		1	0.05	1	0.56	0.56
Oligodendroglioma		3	0.14	3	0.56	2.00
Choroid Plexus Papilloma		1	0.05	1	1.11	1.11
SPINAL CORD	30	2146				
Astrocytoma, Malignant		3	0.14	3	0.77	1.43
Oligodendroglioma		1	0.05	1	0.56	0.56
PERIPHERAL NERVE	30	2146				
Pheochromocytoma, Ganglia		1	0.05	1	1.33	1.33
SKELETAL MUSCLE	30	2146				
Fibroma		1	0.05	1	2.00	2.00
Hemangiosarcoma		1	0.05	1	1.67	1.67
Rhabdomyosarcoma		3	0.14	3	1.43	2.00

		TOTAL		#STUDIES		
		#ORGANS	PERCENT	USING THIS	MINIMUM	MAXIMUM
LOCATION AND TUMOR	#STUDIES	#LESIONS	OF TOTAL	DIAGNOSIS	% FOUND	% FOUND
Sarcoma		1	0.05	1	2.00	2.00
Liposarcoma		1	0.05	1	1.33	1.33
BONE	30	2146				
Chondrosarcoma		3	0.14	3	0.87	2.00
Hemangiosarcoma		1	0.05	1	2.00	2.00
Odontoma, Benign		1	0.05	1	1.67	1.67
Osteoma, Benign		2	0.09	2	1.43	2.00
Osteosarcoma		6	0.28	4	1.11	2.67
HEART	30	2146				
Endocardial Schwannoma, Malignant		2	0.09	2	0.77	1.43
Mediastinal Tissue Mesothelioma, Malignant		4	0.19	4	0.91	1.85
Mediastinal Tissue Undifferentiated Sarcoma		1	0.05	1	1.43	1.43
Neurolemmoma, Malignant		1	0.05	1	1.67	1.67
BLOOD VESSEL	30	2076				
BONE MARROW	30	2146				
Lymphoma, Malignant		1	0.05	1	1.43	1.43
SPLEEN	30	2144				
Fibrosarcoma		1	0.05	1	0.77	0.77
Hemangiosarcoma		1	0.05	1	0.56	0.56
Liposarcoma		2	0.09	2	1.43	1.67
THYMUS	30	2111				
Spindle Cell Thymoma		2	0.09	2	1.67	1.79
Thymoma, Malignant		7	0.33	6	0.56	2.67
LYMPH NODES	30	2142				
Hemangioma		2	0.09	2	1.67	2.00
Hemangiosarcoma		4	0.19	2	1.85	4.29
WHOLE BODY/MULTIPLE ORGAN	30	2146				
Hemangioma		4	0.19	3	0.56	3.33
Hemangiosarcoma		2	0.09	2	0.56	1.67
Histiocytic Sarcoma		45	2.10	19	0.77	6.00
Leukemia, Granulocytic		9	0.42	8	0.56	2.86
Leukemia, Mononuclear Cell		1	0.05	1	2.00	2.00
Lymphoma, Lymphocytic		36	1.68	15	0.91	6.00

		TOTAL		#STUDIES		
		#ORGANS	PERCENT	USING THIS	MINIMUM	MAXIMUM
LOCATION AND TUMOR	#STUDIES	#LESIONS	OF TOTAL	DIAGNOSIS	% FOUND	% FOUND
Lymphoma/Leukemia Combined*		16	0.75	1	21.33	21.33
Mesothelioma		2	0.09	1	1.11	1.11
EYE	30	2146				
Amelanotic Melanoma, Benign		2	0.09	2	1.43	1.92
Harderian Gland, Adenoma		1	0.05	1	2.00	2.00
Harderian Gland, Adenocarcinoma		1	0.05	1	1.92	1.92
Lacrimal Gland, Hemangioma		1	0.05	1	1.67	1.67
Leiomyosarcoma		1	0.05	1	1.67	1.67
EAR	30	2146				
Melanoma, Malignant		1	0.05	1	1.67	1.67
Neural Crest Tumor		1	0.05	1	2.00	2.00
Pinna, Papilloma		2	0.09	2	1.43	1.67
Zymbal's Gland, Adenoma		5	0.23	4	1.43	2.86
Zymbal's Gland, Carcinoma		18	0.84	12	0.77	4.44
Ear Duct, Acanthoma		1	0.05	1	1.33	1.33
Ear Duct, Carcinoma		2	0.09	1	2.67	2.67

* Lymphomas and leukemias were reported only as a combined incidence in study 24

Table 4: Neoplasms/Females-104Weeks

		TOTAL		#STUDIES		
		#ORGANS	PERCENT	USING	MINIMUM	MAXIMUM
LOCATION AND TUMOR	#STUDIES	#LESIONS	OF TOTAL	THIS	% FOUND	% FOUND
				DIAGNOSIS		
ORAL CAVITY/TONGUE/LIP	31	2344				
Squamous Cell Papilloma		1	0.04	1	0.87	0.87
Squamous Cell Carcinoma		5	0.21	4	1.00	2.00
Granular Cell Tumor, Benign		1	0.04	1	2.00	2.00
Tooth, Ameloblastoma, Malignant		1	0.04	1	2.00	2.00
Fibrosarcoma, Malignant		1	0.04	1	1.33	1.33
SALIVARY GLAND	31	2344				
Adenocarcinoma		1	0.04	1	2.00	2.00
STOMACH	31	2344				
Nonglandular Mucosa/Squamous Cell Papilloma		3	0.13	3	1.11	1.67
Teratocarcinoma		1	0.04	1	2.00	2.00
Acanthoma		8	0.34	1	10.67	10.67
Adenocarcinoma		1	0.04	1	0.56	0.56
SMALL INTESTINE	31	2344				
Leiomyoma		1	0.04	1	2.00	2.00
Leiomyosarcoma		4	0.17	3	0.87	2.00
Adenocarcinoma		1	0.04	1	1.33	1.33
LARGE INTESTINE/CECUM/ANUS	31	2344				
Leiomyosarcoma		2	0.09	2	1.43	1.67
Lipoma		3	0.13	3	1.43	1.85
LIVER	31	2344				
Bile Duct Adenoma		8	0.34	6	1.43	6.12
Hemangiosarcoma		1	0.04	1	0.50	0.50
Hepatocellular Adenoma		37	1.58	15	0.56	13.33
Hepatocellular Carcinoma		8	0.34	8	0.77	1.67
Histiocytic Sarcoma		2	0.09	1	1.00	1.00
Lymphosarcoma		1	0.04	1	0.50	0.50
GALL BLADDER	31	2344				
MESENTERY	31	2344				
Fibrosarcoma		5	0.21	4	0.91	3.33
Hemangiopericytoma		1	0.04	1	1.43	1.43

		TOTAL		#STUDIES		
		#ORGANS	PERCENT	USING THIS	MINIMUM	MAXIMUM
LOCATION AND TUMOR	#STUDIES	#LESIONS	OF TOTAL	DIAGNOSIS	% FOUND	% FOUND
NASAL CAVITY	31	2344				
LUNG	31	2344				
Adenoma, Alveolar/Bronchiolar		4	0.17	4	0.77	1.43
Adenocarcinoma, Alveolar/Bronchiolar		3	0.13	3	0.77	1.43
Granuloma		3	0.13	1	5.00	5.00
Leiomyoma		1	0.04	1	1.43	1.43
Mesothelioma		1	0.04	1	0.77	0.77
KIDNEY	31	2344				
Adenoma/Tubular Adenoma		1	0.04	1	1.43	1.43
Adenocarcinoma/Tubular Adenocarcinoma		2	0.09	2	0.77	1.85
Lipoma		6	0.26	5	0.50	1.67
Liposarcoma		5	0.21	5	0.77	1.85
Transitional Cell Carcinoma		2	0.09	2	0.50	2.00
Transitional Cell Tumor, Benign		1	0.04	1	1.43	1.43
Mesenchymal Tumor, Malignant		1	0.04	1	1.43	1.43
URINARY BLADDER	31	2344				
Leiomyosarcoma		1	0.04	1	1.43	1.43
Urothelial Papilloma		3	0.13	3	1.33	1.67
Urothelial Carcinoma		2	0.09	2	1.67	2.00
OVARY	31	2343				
Adenoma		1	0.04	1	0.56	0.56
Cystadenocarcinoma		1	0.04	1	2.00	2.00
Granulosa Cell Tumor, Benign		3	0.13	3	0.56	1.67
Granulosa Cell Tumor, Malignant		2	0.09	2	1.67	2.00
Lipoma		1	0.04	1	1.69	1.69
Papilloma		1	0.04	1	1.67	1.67
Sertoli Cell Tumor, Benign		4	0.17	4	1.33	1.96
Thecal Cell Tumor, Benign		5	0.21	5	1.11	2.00
Thecal Cell Tumor, Malignant		3	0.13	3	0.87	1.85
CERVIX	31	2341				
Fibroma		4	0.17	3	0.50	2.30
Fibrosarcoma		1	0.04	1	1.67	1.67
Granular Cell Tumor, Benign		2	0.09	2	1.43	1.43
Polyps		3	0.13	2	1.00	1.43
Stromal Sarcoma		4	0.17	4	0.77	1.43
Mesothelioma		1	0.04	1	1.15	1.15

		TOTAL		#STUDIES		
		#ORGANS	PERCENT	USING THIS	MINIMUM	MAXIMUM
LOCATION AND TUMOR	#STUDIES	#LESIONS	OF TOTAL	DIAGNOSIS	% FOUND	% FOUND
VAGINA	31	2344				
Fibroma		1	0.04	1	1.11	1.11
Granular Cell Tumor, Benign		3	0.13	2	1.43	3.33
Granular Cell Tumor, Malignant		1	0.04	1	1.43	1.43
Leiomyoma		1	0.04	1	2.00	2.00
Leiomyosarcoma		1	0.04	1	1.85	1.85
Schwannoma, Malignant		3	0.13	2	1.33	3.33
Stromal Sarcoma		2	0.09	2	0.87	2.04
Squamous Cell Papilloma		3	0.13	3	0.87	1.67
Squamous Cell Carcinoma		2	0.09	2	1.43	1.67
CLITORAL GLAND	31	2344				
Adenoma		2	0.09	1	3.33	3.33
Squamous Cell Carcinoma		1	0.04	1	1.43	1.43
UTERUS	31	2343				
Adenoma		3	0.13	3	1.43	1.85
Endometrium, Adenocarcinoma		10	0.43	6	0.77	5.33
Endometrial Stromal Polyp		70	2.99	22	0.91	11.67
Fibrosarcoma/Stromal Sarcoma		17	0.73	9	0.56	18.00
Granular Cell Tumor, Benign		1	0.04	1	2.00	2.00
Hemangioma		30	1.28	6	1.43	15.00
Leiomyoma		10	0.43	9	0.56	2.67
Leiomyosarcoma		2	0.09	2	1.33	1.43
Schwannoma, Malignant		1	0.04	1	1.67	1.67
Squamous Cell Carcinoma		1	0.04	1	0.77	0.77
MAMMARY GLAND	31	2342				
Adenoma		162	6.92	25	1.14	32.00
Adenocarcinoma		520	22.20	28	8.57	58.33
Carcinosarcoma		6	0.26	3	1.67	5.00
Fibroadenoma/Fibroma		893	38.13	31	13.33	62.31
Fibrosarcoma		3	0.13	2	1.54	1.67
Lipoma/Adenolipoma		5	0.21	2	2.00	3.08
Neurofibrosarcoma		2	0.09	2	0.77	1.85
SKIN/SUBCUTANEOUS TISSUE	31	2344				
Basal Cell Tumor, Benign		3	0.13	3	1.11	1.67
Chondrosarcoma		1	0.04	1	2.00	2.00
Fibroma		14	0.60	9	0.91	4.29
Fibrosarcoma		8	0.34	8	1.43	2.00
Hemangioma		17	0.73	5	1.67	6.67
Hemangiosarcoma		9	0.38	7	1.00	2.04
Keratoacanthoma		8	0.34	6	1.11	2.86

		TOTAL		#STUDIES		
		#ORGANS	PERCENT	USING THIS	MINIMUM	MAXIMUM
LOCATION AND TUMOR	#STUDIES	#LESIONS	OF TOTAL	DIAGNOSIS	% FOUND	% FOUND
Lipoma		25	1.07	16	0.56	7.14
Myxoma		2	0.09	2	0.87	1.67
Myxosarcoma		10	0.43	4	0.91	5.22
Pilomatrixoma, Benign		1	0.04	1	0.50	0.50
Rhabdomyosarcoma		1	0.04	1	2.00	2.00
Schwannoma, Benign		1	0.04	1	2.00	2.00
Schwannoma, Malignant		3	0.13	3	1.43	2.00
Sebaceous Gland Adenocarcinoma		1	0.04	1	1.43	1.43
Squamous Cell Papilloma		3	0.13	3	1.43	1.67
Squamous Cell Carcinoma		5	0.21	5	0.56	2.00
ADRENAL	31	2344				
Cortex, Adenoma		76	3.24	24	1.43	34.00
Cortex, Carcinoma		17	0.73	10	0.91	4.29
Pheochromocytoma, Benign		45	1.92	20	1.11	10.00
Pheochromocytoma, Malignant		13	0.55	7	1.43	8.33
Schwannoma, Malignant		1	0.04	1	1.43	1.43
PANCREAS	31	2342				
Acinar Cell, Adenoma		4	0.17	3	1.33	3.33
Acinar Cell, Carcinoma		1	0.04	1	1.96	1.96
Islet Cell, Adenoma		80	3.42	25	1.43	14.29
Islet Cell, Carcinoma		26	1.11	14	0.56	5.62
Leiomyosarcoma		1	0.04	1	0.77	0.77
PITUITARY	31	2343				
Adenoma		1662	70.93	31	26.00	92.86
Carcinoma		128	5.46	21	1.43	58.00
Ganglioneuroma		1	0.04	1	0.77	0.77
THYROID	31	2343				
C-Cell, Adenoma		169	7.21	30	2.86	16.67
C-Cell, Carcinoma		20	0.85	9	0.56	11.43
Follicular Cell, Adenoma		27	1.15	18	1.11	6.12
Follicular Cell, Carcinoma		14	0.60	10	0.87	3.33
Ganglioneuroma		1	0.04	1	1.43	1.43
PARATHYROID	31	2329				
Adenoma		25	1.07	14	1.00	4.35
BRAIN	31	2344				
Astrocytoma, Benign		2	0.09	2	0.56	2.04
Astrocytoma, Malignant		9	0.38	4	1.67	2.31

		TOTAL		#STUDIES		
		#ORGANS	PERCENT	USING THIS	MINIMUM	MAXIMUM
LOCATION AND TUMOR	#STUDIES	#LESIONS	OF TOTAL	DIAGNOSIS	% FOUND	% FOUND
Ganglioneuroma, Benign		1	0.04	1	1.67	1.67
Glioma, Malignant		1	0.04	1	1.43	1.43
Granular Cell Tumor, Benign		5	0.21	4	1.00	2.00
Granular Cell Tumor, Malignant		2	0.09	2	1.43	1.67
Meningeal Sarcoma		1	0.04	1	2.00	2.00
Oligodendroglioma, Malignant		5	0.21	4	0.50	2.67
Fibrosarcoma		1	0.04	1	1.33	1.33
SKELETAL MUSCLE	31	2344				
Rhabdomyosarcoma		1	0.04	1	1.67	1.67
Liposarcoma		1	0.04	1	1.33	1.33
BONE	31	2344				
Osteosarcoma		2	0.09	1	2.67	2.67
HEART	31	2344				
Endocardial Schwannoma		4	0.17	1	3.08	3.08
Schwannoma, Malignant		1	0.04	1	1.33	1.33
BONE MARROW	31	2344				
Histiocytic Sarcoma		1	0.04	1	0.50	0.50
SPLEEN	31	2344				
Hemangiosarcoma		1	0.04	1	1.43	1.43
Lymphosarcoma		1	0.04	1	0.50	0.50
THYMUS	31	2344				
Lymphoma, Malignant		1	0.04	1	2.00	2.00
Thymoma, Benign		5	0.21	4	0.50	2.86
Thymoma, Malignant		5	0.21	4	0.77	1.67
LYMPH NODES	31	2344				
Hemangiosarcoma		2	0.09	2	1.67	1.85
Lymphoma, Malignant		1	0.04	1	1.43	1.43
Fibroangioma		1	0.04	1	1.33	1.33
WHOLE BODY/MULTIPLE ORGAN	31	2344				
Hemangiosarcoma		2	0.09	2	1.43	1.67
Histiocytic Sarcoma		21	0.90	13	1.11	3.08
Leukemia, Granulocytic		5	0.21	3	1.43	2.73
Leukemia, Mononuclear Cell		1	0.04	1	0.91	0.91

		TOTAL		#STUDIES		
		#ORGANS	PERCENT	USING THIS	MINIMUM	MAXIMUM
LOCATION AND TUMOR	#STUDIES	#LESIONS	OF TOTAL	DIAGNOSIS	% FOUND	% FOUND
Lymphoma, Lymphocytic		26	1.11	14	1.11	10.00
Lymphosarcoma		2	0.09	1	1.74	1.74
Lymphoma/Leukemia Combined*		11	0.47	1	14.67	14.67
EYE	31	2344				
Amelanotic Melanoma, Benign		1	0.04	1	1.67	1.67
Fibroma		2	0.09	2	1.43	1.43
Squamous Cell Carcinoma		2	0.09	2	1.43	1.67
EAR	31	2344				
Pinna, Papilloma		2	0.09	2	1.43	1.67
Zymbal's Gland, Adenoma		1	0.04	1	1.43	1.43
Zymbal's Gland, Carcinoma		6	0.26	6	1.33	2.00
Ear Duct Carcinoma		6	0.26	1	8.00	8.00
Fibroma		1	0.04	1	1.67	1.67
Neurofibrosarcoma		1	0.04	1	1.43	1.43

* Lymphomas and leukemias were reported only as a combined incidence in study 24

Study Identification	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	
PITUITARY	130	115	60	110	54	50	52	50	60	70	70	70	70	60	50	50	50	50	60	70	60	60	60	75	84	179	59	70	70	70	
Adenoma	1	58	28	37	34	30	22	32	38	34	36	34	49	40	25	23	14	21	29	27	36	37	29	23	29	83	27	39	48	39	
Carcinoma	1		1									2			1	2	18	13	3		1				1						
Craniopharyngioma																							1								
Ganglioneuroma	1																														
Granular Cell Tumor, Malignant											1																				
THYROID	130	115	60	110	54	50	52	50	60	70	70	70	70	60	50	50	50	50	60	70	60	60	60	75	88	178	60	69	70	70	
C-Cell, Adenoma	13	12	3	11		3	6		5	1	9	10	9	1	1	3	5	3	3	6	5	6	5	2	13	8	7	6	8	4	
C-Cell, Carcinoma				2	8	1	1				1	1						1	1			2	2		2	1		2	3	1	
Follicular Cell, Adenoma	3	2	2	4	1	6	2	6	1					4			1	2		3	1	3			5	3	3	3	4	3	
Follicular Cell, Carcinoma	3	1	1	1	2	1	2					2			1	1									1	2				1	
WHOLE BODY/MULTIPLE ORGAN	130	115	60	110	54	50	52	50	60	70	70	70	70	60	50	50	50	50	60	70	60	60	60	75	90	180	60	70	70	70	
Hemangioma	1													2												1					
Hemangiosarcoma																					1					1					
Histiocytic Sarcoma	1	4		4	2				3	2	3	2	1	1	2	1	1	3			1				4	6		1	3		
Leukemia, Granulocytic								1		1	1		2		1	1			1							1					
Leukemia, Mononuclear Cell																		1													
Lymphoma, Lymphocytic	4		1	1	3	3			3		4		2	1	1	1				1						5	5			1	
Lymphoma/Leukemia Combined																								16							
Mesothelioma																										2					

Table 6: Incidence of Neoplasms by Study for Selected Organs/Females

Study Identification	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	
LIVER	130	115	60	110	54	50	51	49	60	70	70	70	70	60	50	50	50	50	60	70	60	60	60	75	90	180	60	70	70	70	200	
Bile Duct Adenoma			1					3	1			1										1						1				
Hemangiosarcoma																															1	
Hepatocellular Adenoma	1			3	1				8	2	1		2	2	3	3			1		1				1	1					7	
Hepatocellular Carcinoma	1	1							1	1	1	1							1					1								
Histiocytic Sarcoma																															2	
Lymphosarcoma																															1	
MAMMARY GLAND	130	115	60	110	54	50	51	49	60	70	70	70	70	60	50	50	50	50	60	70	60	60	60	75	88	180	60	70	70	70	200	
Adenoma	22	10	1			1	1			2	2	2	4	1	16	16	8	8	9	6	4	2	1		1	5	8	2	1		29	
Adenocarcinoma	37	11	12	19	17	13	15	14	35	6	32	33	21	22			11	15	18	6	14	8	10		15	44	7	8	19	17	41	
Carcinosarcoma			1				2		3																							
Fibroadenoma/Fibroma	81	58	17	40	27	23	22	30	8	36	33	37	33	18	21	18	23	23	22	14	26	12	17	35	35	33	16	12	25	18	80	
Fibrosarcoma	2								1																							
Lipoma/Adenolipoma	4					1																										
Neurofibrosarcoma	1				1																											
ADRENAL	130	115	60	110	54	50	51	49	60	70	70	70	70	60	50	50	50	50	60	70	60	60	60	75	90	180	60	70	70	70	200	
Cortex, Adenoma	3	2	1		1			16	1	2	2	1		1	1	1	17	3	2	1	3	1			5		1	1	2	3	5	
Cortex, Carcinoma		2		1	1			2			1	3			1		1									4			1			
Pheochromocytoma, Benign	2	4	1		2	2	2	2		1	3	4		6		1	2					2			1		1	2	1	3	3	
Pheochromocytoma, Malignant					2	2	1		5			1									1	1										
Schwannoma, Malignant																												1				
PANCREAS	130	115	60	110	54	50	51	49	60	70	70	70	70	60	50	50	50	50	60	70	60	60	60	75	89	179	60	70	70	70	200	
Acinar Cell, Adenoma							1													2				1								

Study Identification	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Acinar Cell, Carcinoma							1																								
Islet Cell, Adenoma	3	6	1		3		2	4	1	1	6	10	4		1	3		1	1	1		2		6	3	5	1	2	1	3	9
Islet Cell, Carcinoma	1		1				1			1	2	3	1	2		2			1						5	1			1		4
Leiomyosarcoma	1																														
PITUITARY	130	115	60	110	54	50	51	49	60	70	70	70	70	60	50	50	50	50	60	70	60	60	60	75	90	179	60	70	70	70	200
Adenoma	97	83	40	46	41	46	39	43	43	49	52	53	60	47	30	34	13	16	41	39	47	49	38	40	50	139	48	53	61	65	160
Carcinoma	3		2	3	1				3	1	1	7	4	3	11	8	26	29	8		2		1		9				1	1	4
Ganglioneuroma	1																														
THYROID	130	115	60	110	54	50	51	49	60	70	70	70	70	60	50	50	50	50	60	70	60	60	60	75	90	179	60	70	70	70	200
C-Cell, Adenoma	9	8	7	8	9	4	3		5	4	7	8	2	2	3	2	5	2	2	4	5	6	5	4	10	8	5	6	8	4	14
C-Cell, Carcinoma	1	1		1		2				1																1			8	3	2
Follicular Cell, Adenoma	2	2	1	2	1		1	3		1		1		1	1						1			1	1	2	2		1	3	
Follicular Cell, Carcinoma		1	2	1	1										1						1				1	2			1	3	
Ganglioneuroma										1																					
WHOLE BODY/MULTIPLE ORGAN	130	115	60	110	54	50	51	49	60	70	70	70	70	60	50	50	50	50	60	70	60	60	60	75	90	180	60	70	70	70	200
Hemangiosarcoma																					1							1			
Histiocytic Sarcoma	4		1	3	1				1		2	2			1	1		1	1						1	2					
Leukemia, Granulocytic				3																	1						1				
Leukemia, Mononuclear Cell				1																											
Lymphoma, Lymphocytic					5		1	3	2	2	4	1	2	1		1				1			1		1		1				
Lymphosarcoma		2																													
Lymphoma/Leukemia Combined																								11							