

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 misleading, false positive result (3,6). On the other hand, 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, but such an increase could be biologically meaningful. In each of these instances, historical control data can provide an additional tool for evaluating the biological significance of a data set.

The neoplasm incidence and survival data presented in this publication were gathered from twenty toxicology studies, each with a duration of 104 weeks. The tissues examined were taken from a standard tissue list and 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 (1). All studies were performed in the United States, Europe or Canada by contract laboratories or industrial toxicology facilities. All studies were conducted in support of in-house research or marketing permits. The data sets presented were provided to us by the individual participating laboratories.

PURPOSE:

The purpose of this compilation is to provide some reported incidences of neoplasms and survival data in CrI:CD[®](SD)BR 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 20 studies included in this publication were initiated between 2001 and 2009 at six different industrial or contract testing facilities in the United States, Europe or Canada. All studies used CrI:CD[®](SD)BR rats from Charles River Laboratories. The rats in these studies were from control groups of dietary or gavage 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 0.5% aqueous methylcellulose, 1.0% aqueous carboxymethylcellulose or deionized water as the vehicle control.

Rats included in this publication were 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 12-hour/12-hour light/dark cycle was employed in all studies. These studies were conducted in different facilities and some variation in environmental conditions did occur. 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 were fed a commercial diet such as Purina PMI Certified Rodent Chow 5002.

DATA SETS PRESENTED:

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 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 adrenal, liver, lymphoreticular tissue, mammary gland, pancreas, pituitary and thyroid.

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 20 for males and 20 for females.

Total Number of Organs (#Organs)

This number represents the total number of each type of tissue or organ 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 the indicated lesion type in the specified organ in all studies examined.

Percent of Total

These values represent the percent incidence of a particular lesion/diagnosis among all specimens (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 percentages. 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 (#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 those 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 This 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 of the Society of Toxicologic Pathology Standardized System of Nomenclature and Diagnostic Criteria (2,5,6,7,8).

Brain

ASTROCYTOMA, MALIGNANT: Astrocytoma
TUMOR, GRANULAR CELL: Myoblastoma, Granular Cell

Heart

SCHWANNOMA, MALIGNANT: Neurilemmoma, Malignant

Kidney

CARCINOMA, KIDNEY: Adenocarcinoma, Renal Cell, Carcinoma, Tubular Cell

Lung

BRONCHIOLO-ALVEOLAR ADENOMA: Adenoma, Pulmonary
BRONCHIOLO-ALVEOLAR CARCINOMA: Carcinoma, Pulmonary

Lymphoreticular Tissue

LYMPHOMA, MALIGNANT: Lymphoma, Lymphocytic and Leukemia, Lymphocytic
SARCOMA, HISTIOCYTIC: Histiocytoma, Fibrous Malignant

Ovary

THECAL CELL TUMOR, BENIGN: Thecoma

Pancreas

ADENOMA, ACINAR CELL: Adenoma, Exocrine
CARCINOMA, ACINAR CELL: Carcinoma, Exocrine

Skin

SCHWANNOMA, MALIGNANT: Neurilemmoma, Malignant

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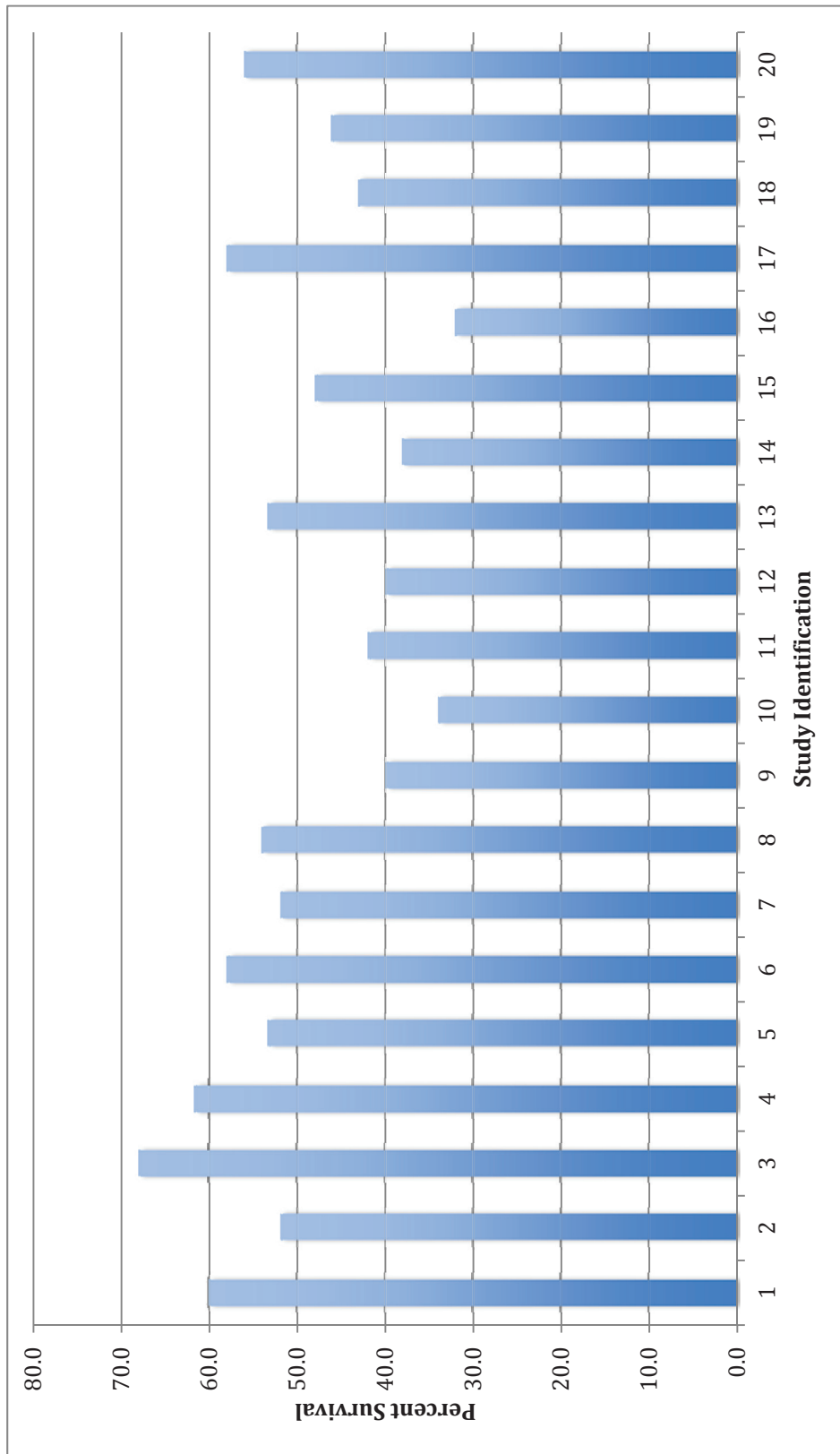
Table 1: Summary of Individual Study Information and Survival/Males-104Weeks

Study Identification	1	2	3	4	5	6	7	8	9	10
Study Initiation Date	2001	2002	2003	2003	2003	2003	2004	2004	2005	2005
Total Number on Study	120	50	100	60	60	50	50	50	60	50
Number Surviving to Termination	72	26	68	37	32	29	26	27	24	17
% Survival	60.0	52.0	68.0	61.7	53.3	58.0	52.0	54.0	40.0	34.0
Study Duration in Weeks	104	104	104	104	104	104	104	104	104	104
Route of Control Article Administration	dietary	dietary	gavage	dietary	gavage	dietary	dietary	dietary	dietary	dietary
Study Identification	11	12	13	14	15	16	17	18	19	20
Study Initiation Date	2005	2005	2005	2006	2007	2007	2008	2008	2008	2009
Total Number on Study	50	65	60	50	50	50	50	65	65	50
Number Surviving to Termination	21	26	32	19	24	16	29	28	30	28
% Survival	42.0	40.0	53.3	38.0	48.0	32.0	58.0	43.1	46.2	56.0
Study Duration in Weeks	104	104	104	104	104	104	104	104	104	104
Route of Control Article Administration	dietary	gavage	gavage	gavage	dietary	dietary	dietary	gavage	gavage	dietary

Table 2: Summary of Individual Study Information and Survival/Females-104 Weeks

Study Identification	1	2	3	4	5	6	7	8	9	10
Study Initiation Date	2001	2002	2003	2003	2003	2003	2004	2004	2005	2005
Total Number on Study	120	50	100	60	60	50	50	50	60	50
Number Surviving to Termination	91	30	59	26	24	28	30	26	26	21
% Survival	75.8	60.0	59.0	43.3	40.0	56.0	60.0	52.0	43.3	42.0
Study Duration in Weeks	104	104	104	104	104	104	104	104	104	104
Route of Control Article Administration	dietary	dietary	gavage	dietary	gavage	dietary	dietary	dietary	dietary	dietary
Study Identification	11	12	13	14	15	16	17	18	19	20
Study Initiation Date	2005	2005	2005	2006	2007	2007	2008	2008	2008	2009
Total Number on Study	50	65	60	50	50	50	50	65	65	50
Number Surviving to Termination	25	21	24	30	27	23	18	30	26	26
% Survival	50.0	32.3	40.0	60.0	54.0	46.0	36.0	46.2	40.0	52.0
Study Duration in Weeks	104	104	104	104	104	104	104	104	104	104
Route of Control Article Administration	dietary	gavage	gavage	gavage	dietary	dietary	dietary	gavage	gavage	dietary

Graph 1: Male Survival-104 Weeks



Graph 2: Female Survival-104 Weeks

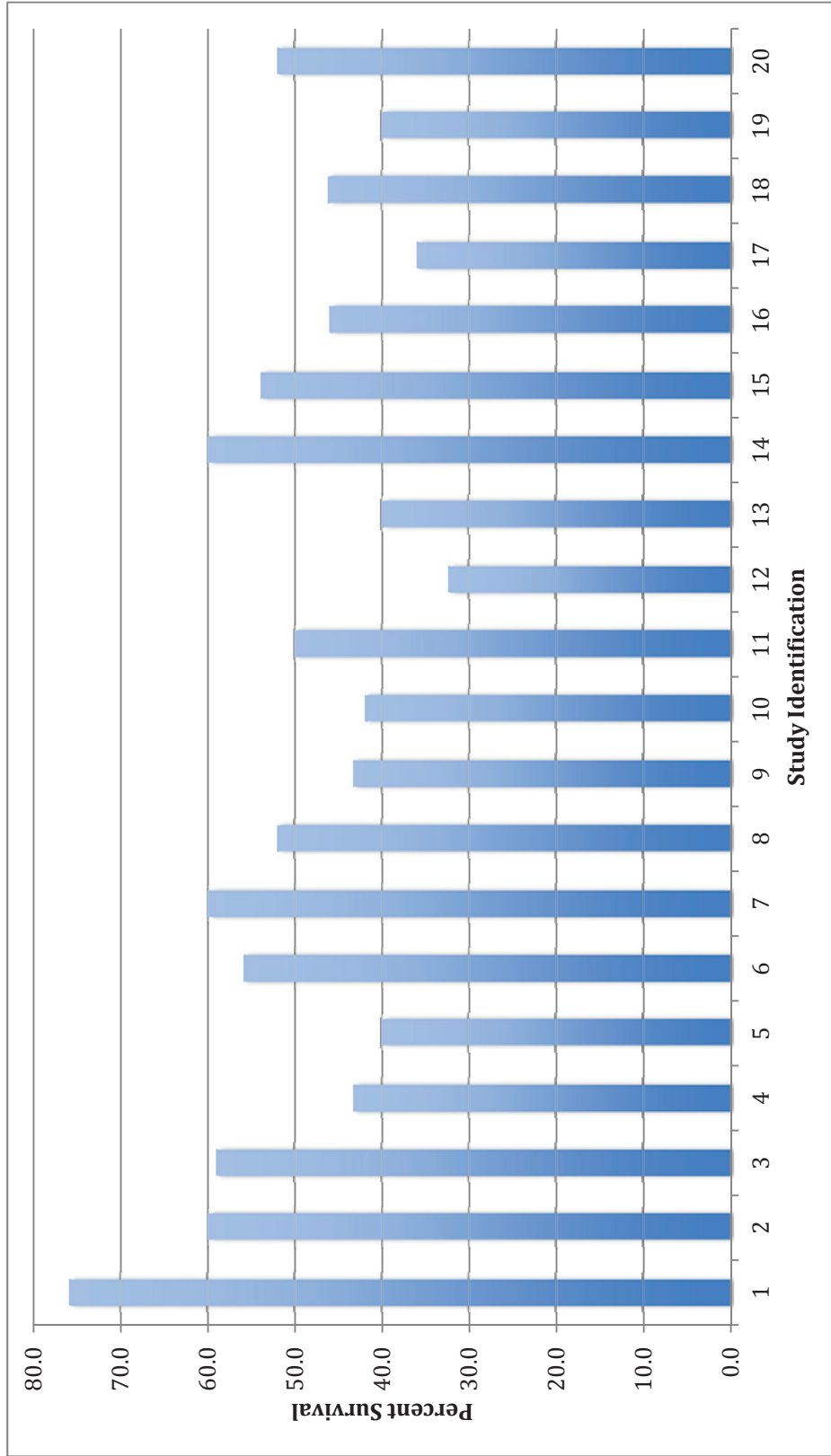


Table 3: Neoplasms/Males-104 Weeks

LOCATION AND TUMOR	TOTAL			#STUDIES USING THIS DIAGNOSIS	MINIMUM % FOUND	MAXIMUM % FOUND
	#STUDIES	#ORGANS #LESIONS	PERCENT OF TOTAL			
ABDOMINAL CAVITY/WALL	20	1205				
Lipoma		2	0.17	2	1.54	2.00
Fibrosarcoma		2	0.17	2	1.54	2.00
ADRENAL	20	1205				
Adenoma, Cortex		22	1.83	11	1.67	6.00
Adenocarcinoma, Cortex		3	0.25	3	0.83	2.00
Pheochromocytoma, Benign		144	11.95	20	0.83	28.00
Pheochromocytoma, Malignant		23	1.91	10	1.67	6.00
Ganglioneuroma		1	0.08	1	2.00	2.00
BLOOD VESSEL	20	1205				
Hemangioma		5	0.41	2	4.00	5.00
Hemangiosarcoma		2	0.17	2	2.00	2.00
BONE	20	1205				
Fibrosarcoma		1	0.08	1	2.00	2.00
Osteosarcoma		7	0.58	7	1.54	2.00
BRAIN	20	1205				
Astrocytoma, Malignant		12	1.00	11	1.54	3.08
Meningioma		2	0.17	2	1.67	1.67
Oligodendroglioma, Malignant		8	0.66	5	1.54	8.00
Schwannoma, Malignant		1	0.08	1	1.54	1.54
EPIDIDYMIS	20	1205				
Mesothelioma		1	0.08	1	1.54	1.54
HEART	20	1205				
Carcinoid, Benign		1	0.08	1	1.54	1.54
Hemangiosarcoma		3	0.25	2	2.00	2.00
Schwannoma, Benign		1	0.08	1	1.54	1.54
Schwannoma, Malignant		1	0.08	1	1.54	1.54
KIDNEY	20	1205				
Carcinoma, Kidney		3	0.25	3	1.00	2.00
Adenoma, Tubular Cell		1	0.08	1	1.00	1.00
Lipoma		7	0.58	6	1.00	4.00
Liposarcoma		3	0.25	3	1.54	2.00
	20	1205				

Table 3: Neoplasms/Males (cont'd.)

LOCATION AND TUMOR	TOTAL			#STUDIES USING THIS DIAGNOSIS	MINIMUM % FOUND	MAXIMUM % FOUND
	#STUDIES	#ORGANS #LESIONS	PERCENT OF TOTAL			
LARGE INTESTINE/CECUM/ANUS						
Fibrosarcoma		1	0.08	1	1.67	1.67
Leiomyosarcoma		1	0.08	1	2.00	2.00
LIVER	20	1205				
Adenoma, Hepatocellular		24	1.99	9	1.00	6.15
Carcinoma, Hepatocellular		11	0.91	8	1.67	2.50
Hemangiosarcoma		7	0.58	2	1.54	5.00
LUNG	20	1205				
Bronchiolo-Alveolar Adenoma		3	0.25	3	1.54	2.00
Bronchiolo-Alveolar Carcinoma		5	0.41	4	1.54	3.33
LYMPHORETICULAR TISSUE	20	1205				
Leukemia, Granular Lymphoblastic		7	0.58	2	3.33	6.00
Leukemia, Monocytic		5	0.41	5	1.54	2.00
Leukemia, Myeloid		6	0.50	4	1.54	4.00
Lymphoma, Malignant		8	0.66	4	1.54	4.00
Sarcoma, Histiocytic		12	1.00	8	1.00	4.00
LYMPH NODES	20	1205				
Hemangioma		6	0.50	5	1.00	4.00
Hemangiosarcoma		7	0.58	3	1.00	7.69
MAMMARY GLAND	20	1205				
Adenoma		1	0.08	1	1.54	1.54
Adenocarcinoma		2	0.17	2	1.54	2.00
Carcinosarcoma		1	0.08	1	2.00	2.00
Fibroadenoma, Benign		9	0.75	6	1.67	4.00
Lipoma		1	0.08	1	2.00	2.00
Mixed Cell Tumor, Malignant		1	0.08	1	1.00	1.00
MESENTERY	20	1205				
Mesothelioma		1	0.08	1	1.67	1.67
ORAL CAVITY	20	1205				
Papilloma		1	0.08	1	1.54	1.54
Carcinoma, Squamous Cell		1	0.08	1	1.67	1.67
PANCREAS	20	1205				
Adenoma, Acinar Cell		6	0.50	4	1.54	2.00
Adenoma, Islet Cell		94	7.8	20	0.83	16.00
Adenocarcinoma, Islet Cell		9	0.75	6	1.54	2.50
Adenoma, Mixed Cell		1	0.08	1	2.00	2.00
PARATHYROID	20	1205				
Adenoma		15	1.24	9	1.54	6.00

Table 3: Neoplasms/Males (cont'd.)

LOCATION AND TUMOR	TOTAL			#STUDIES USING THIS DIAGNOSIS	MINIMUM % FOUND	MAXIMUM % FOUND
	#STUDIES	#ORGANS #LESIONS	PERCENT OF TOTAL			
PITUITARY	20	1205				
Adenoma, Anterior Pituitary		726	60.25	20	41.00	84.00
Carcinoma, Anterior Pituitary		8	0.66	5	1.67	4.00
PROSTATE	20	1205				
Adenoma		1	0.08	1	2.00	2.00
Adenocarcinoma		5	0.41	4	1.67	3.33
SKIN	20	1205				
Keratoacanthoma		61	5.06	18	1.54	14.00
Trichoepithelioma		2	0.17	2	1.00	2.00
Adenoma, Basal Cell		16	1.33	12	1.54	5.00
Carcinoma, Basal Cell		3	0.25	3	0.83	2.00
Adenoma, Sebaceous Cell		6	0.50	4	1.67	3.00
Papilloma, Squamous Cell		23	1.91	11	1.67	10.00
Carcinoma, Squamous Cell		16	1.33	8	1.54	6.67
Fibroma		89	7.39	18	1.67	28.00
Fibrolipoma		1	0.08	1	1.00	1.00
Fibrosarcoma		21	1.74	11	1.00	6.00
Fibrous Histiocytoma		1	0.08	1	2.00	2.00
Hemangiosarcoma		1	0.08	1	1.67	1.67
Lipoma		48	3.98	13	1.67	10.00
Neurofibrosarcoma		8	0.66	4	2.00	5.00
Rhabdomyosarcoma		1	0.08	1	1.00	1.00
SMALL INTESTINE	20	1205				
Leiomyosarcoma		1	0.08	1	1.67	1.67
SPINAL CORD	20	1205				
Astrocytoma		1	0.08	1	2.00	2.00
Ependymoma		1	0.08	1	2.00	2.00
Meningioma		1	0.08	1	2.00	2.00
Schwannoma, Benign		1	0.08	1	0.83	0.83
Osteosarcoma		1	0.08	1	1.54	1.54
SPLEEN	20	1205				
Hemangiosarcoma		4	0.33	4	1.54	2.00
STOMACH	20	1205				
Carcinoma, Squamous Cell		4	0.33	3	2.00	3.33
Fibroma		1	0.08	1	2.00	2.00
Leiomyosarcoma		1	0.08	1	1.00	1.00
TESTIS	20	1205				
Adenoma, Interstitial Cell		48	3.98	15	1.54	22.00
Sertoli Cell Tumor		2	0.17	2	1.00	1.54
Lipoma		0	0.00	0	0.00	0.00

Table 3: Neoplasms/Males (cont'd.)

LOCATION AND TUMOR	TOTAL			#STUDIES USING THIS DIAGNOSIS	MINIMUM % FOUND	MAXIMUM % FOUND
	#STUDIES	#ORGANS #LESIONS	PERCENT OF TOTAL			
THYMUS	20	1205				
Thymoma, Benign		2	0.17	2	2.00	2.00
THYROID	20	1205				
Adenoma, C-Cell		114	9.46	20	2.00	23.08
Adenocarcinoma, C-Cell		4	0.33	4	1.67	2.00
Adenoma, Follicular Cell		27	2.24	14	1.00	8.00
Cystadenoma, Follicular Cell		7	0.58	3	2.00	6.15
Adenocarcinoma, Follicular Cell		2	0.17	2	1.54	1.67
URINARY BLADDER	20	1205				
Papilloma, Transitional Cell		4	0.33	4	1.54	2.00
ZYMBAL'S GLAND	20	1205				
Carcinoma		5	0.41	2	1.54	6.15

Table 4: Neoplasms/Females-104Weeks

LOCATION AND TUMOR	TOTAL			#STUDIES USING THIS DIAGNOSIS	MINIMUM % FOUND	MAXIMUM % FOUND
	#STUDIES	#ORGANS #LESIONS	PERCENT OF TOTAL			
ADRENAL	20	1205				
Adenoma, Cortex		56	4.65	16	1.54	20.00
Adenocarcinoma, Cortex		4	0.33	3	1.67	3.08
Pheochromocytoma, Benign		30	2.49	15	1.54	8.00
Pheochromocytoma, Malignant		1	0.08	1	1.54	1.54
BLOOD VESSEL	20	1205				
Hemangiosarcoma		2	0.17	2	1.67	2.00
BONE	20	1205				
Osteosarcoma		6	0.50	4	1.54	4.00
BRAIN	20	1205				
Astrocytoma, Malignant		4	0.33	3	2.00	3.08
Medulloblastoma, Malignant		1	0.08	1	1.54	1.54
Meningioma		1	0.08	1	2.00	2.00
Tumor, Granular Cell		1	0.08	1	2.00	2.00
CERVIX	20	1205				
Carcinoma, Squamous Cell		9	0.75	9	1.67	2.00
EAR	20	1205				
Neural Crest Tumor, Malignant		1	0.08	1	1.00	1.00
HEART	20	1205				
Hemangiosarcoma		1	0.08	1	1.00	1.00
Schwannoma, Benign		1	0.08	1	2.00	2.00
Schwannoma, Malignant		1	0.08	1	2.00	2.00
KIDNEY	20	1205				
Fibrosarcoma		2	0.17	2	2.00	2.00
Lipoma		1	0.08	1	1.54	1.54
Liposarcoma		3	0.25	1	4.62	4.62
Mesenchymal Tumor, Benign		1	0.08	1	1.54	1.54
LARGE INTESTINE/CECUM/ANUS	20	1205				
Fibrosarcoma		1	0.08	1	1.67	1.67
Leiomyoma		1	0.08	1	1.54	1.54
Lipoma		2	0.17	2	2.00	2.00
LIVER	20	1205				
Adenoma, Hepatocellular		26	2.16	10	1.00	10.00
Hemangiosarcoma		2	0.17	1	2.00	2.00

Table 4: Neoplasms/Females (cont'd.)

LOCATION AND TUMOR	TOTAL			#STUDIES USING THIS DIAGNOSIS	MINIMUM % FOUND	MAXIMUM % FOUND
	#STUDIES	#ORGANS #LESIONS	PERCENT OF TOTAL			
LUNG	20	1205				
Bronchiolo-Alveolar Adenoma		3	0.25	3	1.67	2.00
Carcinoma, Squamous Cell		1	0.08	1	2.00	2.00
LYMPHORETICULAR TISSUE	20	1205				
Histiocytoma, Fibrous Malignant		2	0.17	1	4.00	4.00
Leukemia, Myeloid		1	0.08	1	1.67	1.67
Lymphoma, Malignant		4	0.33	3	1.54	2.00
Sarcoma, Histiocytic		7	0.58	6	1.00	3.08
LYMPH NODES	20	1205				
Hemangioma		1	0.08	1	1.67	1.67
Hemangiosarcoma		1	0.08	1	1.54	1.54
MAMMARY GLAND	20	1205				
Adenoma		62	5.15	17	0.83	13.33
Adenocarcinoma		111	9.21	19	1.67	27.69
Fibroadenoma, Benign		394	32.70	19	7.69	68.00
Fibroma, Benign		2	0.17	2	1.00	1.67
Mixed Cell Tumor, Malignant		1	0.08	1	1.00	1.00
OVARY	20	1205				
Adenoma, Tubular		2	0.17	2	1.67	2.00
Cystadenoma		1	0.08	1	1.54	1.54
Granulosa Cell Tumor, Benign		2	0.17	2	1.54	2.00
Granulosa Cell Tumor, Malignant		1	0.08	1	1.54	1.54
Granulosa-Thecal Cell Tumor, Benign		1	0.08	1	2.00	2.00
Thecal Cell Tumor, Benign		6	0.50	3	1.54	4.00
Fibroleiomyoma, Benign		2	0.17	2	2.00	2.00
Luteoma, Benign		1	0.08	1	1.00	1.00
Sertoli Cell Tumor, Benign		1	0.08	1	1.54	1.54
PANCREAS	20	1205				
Adenoma, Islet Cell		40	3.32	17	1.54	10.00
Carcinoma, Acinar Cell		2	0.17	2	1.54	2.00
PARATHYROID	20	1205				
Adenoma		6	0.50	5	2.00	4.00
PITUITARY	20	1205				
Adenoma, Anterior Pituitary		774	64.23	20	40.00	84.00
Carcinoma, Anterior Pituitary		23	1.91	8	2.00	9.23
SKELETAL MUSCLE	20	1205				
Liposarcoma		1	0.08	1	1.00	1.00
Sarcoma		1	0.08	1	1.00	1.00

Table 4: Neoplasms/Females (cont'd.)

LOCATION AND TUMOR	TOTAL			#STUDIES USING THIS DIAGNOSIS	MINIMUM % FOUND	MAXIMUM % FOUND
	#STUDIES	#ORGANS #LESIONS	PERCENT OF TOTAL			
SKIN	20	1205				
Keratoacanthoma		5	0.41	5	1.00	2.00
Adenoma, Basal Cell		2	0.17	2	2.00	2.00
Papilloma, Squamous Cell		7	0.58	4	1.00	5.00
Fibroma		22	1.83	13	0.83	6.00
Fibrolipoma		1	0.08	1	1.00	1.00
Fibrosarcoma		6	0.50	6	1.67	2.00
Hemangioma		2	0.17	2	1.67	2.00
Hemangiosarcoma		3	0.25	3	1.54	2.00
Lipoma		22	1.83	10	1.00	8.00
Liposarcoma		1	0.08	1	1.54	1.54
Schwannoma, Malignant		2	0.17	2	0.83	2.00
Sarcoma		1	0.08	1	2.00	2.00
SMALL INTESTINE	20	1205				
Fibrosarcoma		1	0.08	1	1.67	1.67
Lipoma		1	0.08	1	2.00	2.00
SPINAL CORD	20	1205				
Osteosarcoma		1	0.08	1	1.00	1.00
SPLEEN	20	1205				
Hemangioma		1	0.08	1	2.00	2.00
Hemangiosarcoma		4	0.33	3	1.54	3.08
THYMUS	20	1205				
Thymoma, Benign		1	0.08	1	2.00	2.00
Thymoma, Malignant		1	0.08	1	2.00	2.00
Mesothelioma		2	0.17	2	2.00	2.00
THYROID	20	1205				
Adenoma, C-Cell		90	7.47	20	1.67	16.00
Carcinoma, C-Cell		7	0.58	5	1.54	3.33
Adenoma, Follicular Cell		13	1.08	11	1.54	4.00
Cystadenoma, Follicular Cell		1	0.08	1	1.67	1.67
URINARY BLADDER	20	1205				
Carcinoma, Transitional Cell		2	0.17	2	2.00	2.00
UTERUS	20	1205				
Adenoma, Endometrial		6	0.50	5	1.00	3.08
Adenocarcinoma		3	0.25	2	1.54	3.08
Carcinoma, Squamous		5	0.41	3	2.00	4.00
Stromal Polyp		14	1.16	3	3.00	9.23

Table 5: Incidence of Neoplasms by Study for Selected Organs/Males

STUDY IDENTIFICATION #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
ADRENAL	120	50	100	60	60	50	50	50	60	50	50	65	60	50	50	50	50	65	65	50
Adenoma, Cortex		2			3	1	1		1	1		1	2	1		3		2	3	3
Adenocarcinoma, Cortex	1																			
Pheochromocytoma, Benign	1	3	10	11	2	9	7	5	3	8	6	12	8	11	8	6	14	11	7	2
Pheochromocytoma, Malignant			6		2	2	1		3			2	1		1		3	2	2	
Ganglioneuroma										1										
LIVER	120	50	100	60	60	50	50	50	60	50	50	65	60	50	50	50	50	65	65	50
Adenoma, Hepatocellular	7	3	1				1		2		1		2			3		4		
Carcinoma, Hepatocellular	3		2		1		1			1	1				1					1
Hemangiosarcoma	6																	1		
LYMPHORETICULAR TISSUE	120	50	100	60	60	50	50	50	60	50	50	65	60	50	50	50	50	65	65	50
Leukemia, Granular Lymphoblastic	4											1		1	3					
Leukemia, Monocytic				1				1	1			1								
Leukemia, Myeloid					2					2			1					1		
Lymphoma, Malignant			4														2	1		1
Sarcoma, Histiocytic	2	1	1			1		2				2			2				1	
MAMMARY GLAND	120	50	100	60	60	50	50	50	60	50	50	65	60	50	50	50	50	65	65	50
Adenoma																		1		
Adenocarcinoma																	1	1		
Carcinosarcoma																1				
Fibroadenoma, Benign		1	2						2		1		1	2						
Lipoma																				1
Mixed Cell Tumor, Malignant																				
PANCREAS	120	50	100	60	60	50	50	50	60	50	50	65	60	50	50	50	50	65	65	50
Adenoma, Acinar Cell	2		2	1																1
Adenoma, Islet Cell	1	7	5	6	3	2	5	2	4	8	2	6	7	8	6	3	6	3	6	4
Adenocarcinoma, Islet Cell	3		2			1					1				1	1		1		

Table 5: Incidence of Neoplasms by Study for Selected Organs/Males (cont'd)

STUDY IDENTIFICATION #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Adenoma, Mixed Cell																	1			
PITUITARY	120	50	100	60	60	50	50	50	60	50	50	65	60	50	50	50	50	65	65	50
Adenoma, Anterior Pituitary	71	28	41	26	36	30	31	39	43	31	29	33	35	42	41	35	37	28	31	39
Carcinoma, Anterior Pituitary				1							2		1					2	2	
THYROID	120	50	100	60	60	50	50	50	60	50	50	65	60	50	50	50	50	65	65	50
Adenoma, C-Cell	3	9	2	7	3	2	5	4	8	9	4	5	3	7	5	3	7	7	15	6
Adenocarcinoma, C-Cell						1					1		1				1			
Adenoma, Follicular Cell		3	1		2	2			1	2		1	1		3	2	4	2	2	1
Cystadenoma, Follicular Cell												4		2	1					
Adenocarcinoma, Follicular Cell				1								1								

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
ADRENAL	120	50	100	60	60	50	50	50	60	50	50	65	60	50	50	50	50	65	65	50
Adenoma, Cortex		7		2	1		1	4	3	1	8	2	1		6	10	5	1	3	1
Adenocarcinoma, Cortex					1										1				2	
Pheochromocytoma, Benign		3	3	1		2	4	1		1	2	4	1	3		2	1	1	1	
Pheochromocytoma, Malignant																			1	
LIVER	120	50	100	60	60	50	50	50	60	50	50	65	60	50	50	50	50	65	65	50
Adenoma, Hepatocellular	3	3	1			5	1		4		5		2		1			1		
Hemangiosarcoma			2																	
LYMPHORETICULAR TISSUE	120	50	100	60	60	50	50	50	60	50	50	65	60	50	50	50	50	65	65	50
Histiocytoma, Fibrous Malignant																	2			
Leukemia, Myeloid				1																
Lymphoma, Malignant			2		1													1		
Sarcoma, Histiocytic			1	1							1				1			2	1	
MAMMARY GLAND	120	50	100	60	60	50	50	50	60	50	50	65	60	50	50	50	50	65	65	50
Adenoma	1	1	12	7	8	2	4	2	1	3	5	1		3	2			4	5	1
Adenocarcinoma		2	23	2	5	7	3	3	4	1	8	3	1	5	4	6	1	18	14	1
Fibroadenoma, Benign		9	56	11	24	16	19	10	8	32	17	5	26	24	13	34	19	33	27	11
Fibroma, Benign			1		1															
Mixed Cell Tumor, Malignant			1																	
PANCREAS	120	50	100	60	60	50	50	50	60	50	50	65	60	50	50	50	50	65	65	50
Adenoma, Islet Cell	3	1	4	3		2	1	2	1	4	3	2	2		1	5	2		1	3
Carcinoma, Acinar Cell																1		1		
PITUITARY	120	50	100	60	60	50	50	50	60	50	50	65	60	50	50	50	50	65	65	50
Adenoma, Anterior Pituitary	68	37	46	24	39	42	38	27	46	35	31	46	45	38	27	32	37	45	41	30
Carcinoma, Anterior Pituitary		1	7				1					2		1			2	3	6	

Table 6: Incidence of Neoplasms by Study for Selected Organs/Females (cont'd)

STUDY IDENTIFICATION #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
THYROID	120	50	100	60	60	50	50	50	60	50	50	65	60	50	50	50	50	65	65	50
Adenoma, C-Cell	5	1	6	4	8	6	8	3	2	6	8	2	1	4	7	3	3	4	5	4
Carcinoma, C-Cell						1			2			2		1						
Adenoma, Follicular Cell		1			1			1	1		1		2		1	1	1		1	2
Cystadenoma, Follicular Cell													1							

