

Appendix: Statistics

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Historical Control Data on Neoplastic Findings in HsdRccHanTM: WIST, Wistar Hannover Rats from 2 years Bioassays (Sacrifice Schedule: < 103 Weeks)

Brain

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Brain						
Numbers of rats examined	389					
Astrocytoma	2	0.51	0.40	1.38	0.00	5.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Brain						
Numbers of rats examined	390					
Astrocytoma	0	0.00	0.00	0.00	0.00	0.00

Spinal Cord and Optic Nerves

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Spinal cord						
Numbers of rats examined	410					
Metastatic sarcoma	20	4.88	4.00	20.00	0.00	100.00
Optic nerves						
Numbers of rats examined	254					

* value due to single gross lesions

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Spinal cord						
Numbers of rats examined	410					
Metastatic sarcoma	2	0.49	0.80	2.77	0.00	10.00
Optic nerves						
Numbers of rats examined	257					

Eyes, Harderian Glands and Extraorbital Lacrimal Glands

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Eyes						
Numbers of rats examined	410					
Harderian glands						
Numbers of rats examined	410					
Exorbital lacrimal glands						
Numbers of rats examined	107					

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Eyes						
Numbers of rats examined	410					
Harderian glands						
Numbers of rats examined	410					
Exorbital lacrimal glands						
Numbers of rats examined	90					

Aorta, Other Blood Vessels, Heart, Trachea and Lungs

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Aorta						
Numbers of rats examined	408					
Liposarcoma	1	0.25	0.10	0.50	0.00	2.50
Other blood vessels*						
Numbers of rats examined	10					
Heart						
Numbers of rats examined	390					
Trachea						
Numbers of rats examined	370					
Lungs						
Numbers of rats examined	390					
Metastatic carcinoma	0	0.00	0.00	0.00	0.00	0.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Aorta						
Numbers of rats examined	409					
Liposarcoma	0	0.00	0.00	0.00	0.00	0.00
Other blood vessels*						
Numbers of rats examined	10					
Heart						
Numbers of rats examined	390					
Trachea						
Numbers of rats examined	370					
Lungs						
Numbers of rats examined	389					
Metastatic carcinoma	0	0.00	0.00	0.00	0.00	0.00

* organs sampled in single studies only

Pituitary Gland, Adrenals, Adrenal Cortex and Adrenal Medulla

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
<u>Pituitary Gland</u>						
Numbers of rats examined	383					
Adenoma	15	3.92	4.64	7.41	0.00	33.33
Adenoma of pars intermedia	0	0.00	0.00	0.00	0.00	0.00
Adenoma: pars anterior	2	0.52	0.38	1.96	0.00	10.00
<u>Adrenals</u>						
Numbers of rats examined	370					
Cortical adenoma	1	0.27	0.42	2.04	0.00	10.00
<u>Adrenal cortex</u>						
Numbers of rats examined	400					
Adenoma	1	0.25	0.40	2.00	0.00	10.00
<u>Adrenal medulla</u>						
Numbers of rats examined	387					
Pheochromocytoma (b)	0	0.00	0.00	0.00	0.00	0.00
Pheochromocytoma (m)	0	0.00	0.00	0.00	0.00	0.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
<u>Pituitary Gland</u>						
Numbers of rats examined	396					
Adenoma	56	14.14	12.19	8.26	0.00	28.21
Adenoma of pars intermedia	0	0.00	0.00	0.00	0.00	0.00
Adenoma: pars anterior	0	0.00	0.00	0.00	0.00	0.00
<u>Adrenals</u>						
Numbers of rats examined	370					
Cortical adenoma	0	0.00	0.00	0.00	0.00	0.00
<u>Adrenal cortex</u>						
Numbers of rats examined	410					
Adenoma	1	0.24	0.20	1.00	0.00	5.00
<u>Adrenal medulla</u>						
Numbers of rats examined	368					
Pheochromocytoma (b)	2	0.54	0.22	1.04	0.00	5.00
Pheochromocytoma (m)	0	0.00	0.00	0.00	0.00	0.00

Thyroid Glands and Parathyroid Glands

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Thyroid glands						
Numbers of rats examined	399					
C-cell adenoma	0	0.00	0.00	0.00	0.00	0.00
Follicular cell adenoma	3	0.75	0.58	2.04	0.00	10.00
Follicular cell carcinoma	2	0.50	0.19	0.98	0.00	5.00
Parathyroid glands						
Numbers of rats examined	319					

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Thyroid glands						
Numbers of rats examined	397					
C-cell adenoma	6	1.51	1.54	4.42	0.00	20.00
Follicular cell adenoma	1	0.25	0.10	0.52	0.00	2.63
Follicular cell carcinoma	0	0.00	0.00	0.00	0.00	0.00
Parathyroid glands						
Numbers of rats examined	322					

Pancreas and Liver

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Pancreas						
Numbers of rats examined	408					
Adenoma	2	0.49	0.21	0.71	0.00	2.63
Islet cell adenoma	1	0.25	0.40	2.00	0.00	10.00
Liver						
Numbers of rats examined	410					
Hepatocellular adenoma	2	0.49	0.20	1.00	0.00	5.00
Hepatocellular carcinoma	2	0.49	0.20	1.00	0.00	5.00
Hepatocytic nodule	0	0.00	0.00	0.00	0.00	0.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Pancreas						
Numbers of rats examined	408					
Adenoma	0	0.00	0.00	0.00	0.00	0.00
Islet cell adenoma	0	0.00	0.00	0.00	0.00	0.00
Liver						
Numbers of rats examined	398					
Hepatocellular adenoma	0	0.00	0.00	0.00	0.00	0.00
Hepatocellular carcinoma	0	0.00	0.00	0.00	0.00	0.00
Hepatocytic nodule	4	1.01	0.40	2.00	0.00	10.00

Esophagus, Stomach, Duodenum, Jejunum and Ileum

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
<u>Esophagus</u>						
Numbers of rats examined	410					
<u>Stomach</u>						
Numbers of rats examined	390					
<u>Duodenum</u>						
Numbers of rats examined	410					
<u>Jejunum</u>						
Numbers of rats examined	410					
<u>Ileum</u>						
Numbers of rats examined	330					

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
<u>Esophagus</u>						
Numbers of rats examined	410					
<u>Stomach</u>						
Numbers of rats examined	390					
<u>Duodenum</u>						
Numbers of rats examined	410					
<u>Jejunum</u>						
Numbers of rats examined	410					
<u>Ileum</u>						
Numbers of rats examined	330					

Cecum, Colon and Rectum

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
<u>Cecum</u>						
Numbers of rats examined	410					
<u>Colon</u>						
Numbers of rats examined	410					
<u>Rectum</u>						
Numbers of rats examined	370					

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
<u>Cecum</u>						
Numbers of rats examined	409					
<u>Colon</u>						
Numbers of rats examined	409					
<u>Rectum</u>						
Numbers of rats examined	369					

Sublingual and Submandibular Glands

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Subl. and Submand. glands						
Numbers of rats examined	430					

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Subl. and Submand. glands						
Numbers of rats examined	430					

Kidneys and Urinary Bladder

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Kidneys						
Numbers of rats examined	380					
Urinary bladder						
Numbers of rats examined	380					

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Kidneys						
Numbers of rats examined	380					
Urinary bladder						
Numbers of rats examined	380					

Skin and Subcutis*

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Skin and Subcutis						
Numbers of rats examined	389					
Papilloma	2	0.51	0.80	2.77	0.00	10.00
Keratocanthoma	1	0.26	0.10	0.50	0.00	2.50
Fibroma	1	0.26	0.13	0.67	0.00	3.33
Lipoma	1	0.26	0.10	0.50	0.00	2.50
Fibrosarcoma	1	0.26	0.10	0.50	0.00	2.50
Schwannoma (m)	2	0.51	0.83	2.82	0.00	10.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Skin and Subcutis						
Numbers of rats examined	410					
Papilloma	0	0.00	0.00	0.00	0.00	0.00
Keratocanthoma	0	0.00	0.00	0.00	0.00	0.00
Fibroma	1	0.24	0.19	0.98	0.00	5.00
Lipoma	0	0.00	0.00	0.00	0.00	0.00
Fibrosarcoma	0	0.00	0.00	0.00	0.00	0.00
Schwannoma (m)	0	0.00	0.00	0.00	0.00	0.00

* in single studies, gross lesions examined only

Testes, Epididymides, Prostate Gland and Seminal Vesicles

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Testes						
Numbers of rats examined	409					
Leydig cell tumor (b)	2	0.49	0.30	1.10	0.00	5.00
Epididymides						
Numbers of rats examined	410					
Prostate gland						
Numbers of rats examined	410					
Seminal vesicles						
Numbers of rats examined	370					

Mammary Glands

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Mammary glands						
Numbers of rats examined	249					
Fibroadenoma	2	0.80	0.38	1.48	0.00	5.71
Adenocarcinoma	0	0.00	0.00	0.00	0.00	0.00

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Mammary glands						
Numbers of rats examined	407					
Fibroadenoma	10	2.46	1.63	4.18	0.00	15.00
Adenocarcinoma	3	0.74	0.48	1.42	0.00	5.00

* in single studies, gross lesions examined only

Ovaries, Uterus and Vagina

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Ovaries						
Numbers of rats examined	390					
Uterus						
Numbers of rats examined	419					
Polyp, adenomatous	1	0.24	0.10	0.49	0.00	2.50
Polyp, endometrial	3	0.72	1.15	5.88	0.00	30.00
Polyp, stromal	12	2.86	1.73	5.09	0.00	20.00
Adenocarcinoma	1	0.24	0.19	0.98	0.00	5.00
Yolk sac carcinoma	1	0.24	0.19	0.98	0.00	5.00
Vagina						
Numbers of rats examined	133					
Polyp, stromal	3	2.26	22.22	44.10	0.00	100.00

Hemolymphoreticular System, Bone Marrow (Sternum, Femur) and Spleen

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Hemolymphoretic. system						
Numbers of rats examined	460					
Malignant Lymphoma	5	1.09	0.58	2.16	0.00	10.00
Bone marrow (S. / F.)						
Numbers of rats examined	380					
Spleen						
Numbers of rats examined	360					

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Hemolymphoretic. system						
Numbers of rats examined	450					
Malignant Lymphoma	0	0.00	0.00	0.00	0.00	0.00
Bone marrow (S. / F.)						
Numbers of rats examined	380					
Spleen						
Numbers of rats examined	360					

**Mesenteric Lymph Nodes, Mandibular Lymph Nodes,
Other Lymph Nodes and Thymus**

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Mesenteric lymph nodes*						
Numbers of rats examined	388					
Hemangioma	8	2.06	1.73	4.46	0.00	20.00
Hemangiosarcoma	1	0.26	0.10	0.49	0.00	2.50
Mandibular lymph nodes						
Numbers of rats examined	345					
Hemangiosarcoma	1	0.29	0.28	1.36	0.00	6.67
Other lymph nodes*						
Numbers of rats examined	16					
Hemangiosarcoma	1	6.25	6.25	0.00	6.25	6.25
Metastatic sarcoma	2	12.50	12.50	0.00	12.50	12.50
Hemangioma	2	12.50	6.25	0.00	6.25	6.25
Thymus						
Numbers of rats examined	409					
Thymoma, benign	1	0.24	0.10	0.51	0.00	2.56

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Mesenteric lymph nodes*						
Numbers of rats examined	359					
Hemangioma	5	1.39	1.50	3.39	0.00	10.00
Hemangiosarcoma	0	0.00	0.00	0.00	0.00	0.00
Mandibular lymph nodes						
Numbers of rats examined	332					
Hemangiosarcoma	0	0.00	0.00	0.00	0.00	0.00
Other lymph nodes*						
Numbers of rats examined	36					
Hemangiosarcoma	0	0.00	0.00	0.00	0.00	0.00
Metastatic sarcoma	0	0.00	0.00	0.00	0.00	0.00
Hemangioma	1	2.78	20.00	44.72	0.00	100.00
Thymus						
Numbers of rats examined	409					
Thymoma, benign	0	0.00	0.00	0.00	0.00	0.00

* gross lesions only or organ sampled in single studies only

Bone (Sternum, Femur), Joints, Skeletal Muscle and Tongue

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Bone (S./F.)						
Numbers of rats examined	390					
Joints						
Numbers of rats examined	140					
Skeletal muscle						
Numbers of rats examined	410					
Sarcoma, NOS	0	0.00	0.00	0.00	0.00	0.00
Tongue						
Numbers of rats examined	260					

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Bone (S./F.)						
Numbers of rats examined	390					
Joints						
Numbers of rats examined	140					
Skeletal muscle						
Numbers of rats examined	410					
Sarcoma, NOS	2	0.49	0.80	2.77	0.00	10.00
Tongue						
Numbers of rats examined	260					

Body Cavities and Adipose Tissues

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Body cavities*						
Numbers of rats examined	14					
Lipoma	4	28.57	12.50	35.36	0.00	100.00
Sarcoma, NOS	1	7.14	12.50	35.36	0.00	100.00
Hibernoma	1	7.14	4.17	11.79	0.00	33.33
Adipose tissue*						
Numbers of rats examined	1					

*gross lesions sampled only

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Body cavities*						
Numbers of rats examined	4					
Lipoma	1	25.00	33.33	57.74	0.00	100.00
Sarcoma, NOS	0	0.00	0.00	0.00	0.00	0.00
Hibernoma	0	0.00	0.00	0.00	0.00	0.00
Adipose tissue*						
Numbers of rats examined	0					

*gross lesions sampled only

Sciatic Nerve and Mediast. Lymph Node

Males	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Sciatic nerve						
Numbers of rats examined	410					
Mediast.lymph node						
Numbers of rats examined	2					

Females	Total n	Total %	Mean %	STDEV %	MIN %	MAX %
Sciatic nerve						
Numbers of rats examined	410					
Mediast.lymph node						
Numbers of rats examined	4					