

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 7. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Alimentary System							
Liver * Angiectasis	Simple Incidence	3/49 (6.1%)	6/50 (12.0%)	1/48 (2.1%)	5/50 (10.0%)	5/50 (10.0%)	3/46 (6.5%)
	Poly-K Incidence	3/31.6 (9.5%)	6/32.5 (18.4%)	1/30.9 (3.2%)	5/35.4 (14.1%)	5/35.5 (14.1%)	3/31.9 (9.4%)
	Terminal Incidence	1/11 (9.1%)	3/12 (25.0%)	0/13 (0.0%)	0/13 (0.0%)	3/17 (17.6%)	1/13 (7.7%)
	Time-to-First	662	563	612	555	642	566
	Poly-K P-Value	0.509N	0.248	0.310N	0.418	0.419	0.661N
	Severity Profile	1 2 0 0	1 5 0 0	0 1 0 0	2 3 0 0	2 1 1 1	0 2 1 0
	JT/SW P-Value	0.431	0.151	0.490	0.305	0.308	0.407
	RTE P-Value	0.436	0.142	0.236N	0.243	0.230	0.453
Liver * Basophilic Focus							
Liver * Basophilic Focus	Simple Incidence	22/49 (44.9%)	26/50 (52.0%)	25/48 (52.1%)	28/50 (56.0%)	22/50 (44.0%)	23/46 (50.0%)
	Poly-K Incidence	22/37.9 (58.0%)	26/38.2 (68.0%)	25/38.3 (65.2%)	28/42.7 (65.5%)	22/40.1 (54.9%)	23/37.8 (60.8%)
	Terminal Incidence	6/11 (54.5%)	9/12 (75.0%)	8/13 (61.5%)	7/13 (53.8%)	9/17 (52.9%)	6/13 (46.2%)
	Time-to-First	385	400	461	448	447	463
	Poly-K P-Value	0.353N	0.231	0.326	0.308	0.479N	0.493
Liver * Clear Cell Focus							
Liver * Clear Cell Focus	Simple Incidence	9/49 (18.4%)	10/50 (20.0%)	9/48 (18.8%)	7/50 (14.0%)	13/50 (26.0%)	9/46 (19.6%)
	Poly-K Incidence	9/35.6 (25.3%)	10/32.9 (30.4%)	9/32.5 (27.7%)	7/35.5 (19.7%)	13/38.7 (33.6%)	9/34.0 (26.5%)
	Terminal Incidence	2/11 (18.2%)	6/12 (50.0%)	4/13 (30.8%)	3/13 (23.1%)	5/17 (29.4%)	2/13 (15.4%)
	Time-to-First	467	561	562	473	470	446
	Poly-K P-Value	0.438	0.416	0.521	0.390N	0.294	0.563
Liver * Cyst,Biliary Tract							
Liver * Cyst,Biliary Tract	Simple Incidence	4/49 (8.2%)	1/50 (2.0%)	0/48 (0.0%)	1/50 (2.0%)	2/50 (4.0%)	0/46 (0.0%)
	Poly-K Incidence	4/32.2 (12.4%)	1/31.4 (3.2%)	0/30.5 (0.0%)	1/34.5 (2.9%)	2/34.9 (5.7%)	0/30.9 (0.0%)
	Terminal Incidence	1/11 (9.1%)	0/12 (0.0%)	0/13 (0.0%)	0/13 (0.0%)	2/17 (11.8%)	0/13 (0.0%)
	Time-to-First	624	660	----	540	726 (T)	----
	Poly-K P-Value	0.051N	0.181N	0.064N	0.154N	0.298N	0.062N
Liver * Degeneration,Cystic							
Liver * Degeneration,Cystic	Simple Incidence	2/49 (4.1%)	1/50 (2.0%)	6/48 (12.5%)	5/50 (10.0%)	8/50 (16.0%)	7/46 (15.2%)
	Poly-K Incidence	2/32.0 (6.2%)	1/31.7 (3.2%)	6/32.0 (18.8%)	5/35.3 (14.2%)	8/37.5 (21.3%)	7/32.3 (21.7%)
	Terminal Incidence	0/11 (0.0%)	0/12 (0.0%)	2/13 (15.4%)	0/13 (0.0%)	1/17 (5.9%)	2/13 (15.4%)
	Time-to-First	533	573	458	525	520	593
	Poly-K P-Value	0.007 **	0.504N	0.124	0.253	0.071	0.072
	Severity Profile	2 0 0 0	1 0 0 0	6 0 0 0	5 0 0 0	6 2 0 0	7 0 0 0
	JT/SW P-Value	0.004 **	0.726	0.049 * ¹	0.105	0.020 *	0.036 *
	RTE P-Value	0.004 **	0.365N	0.087	0.157	0.014 *	0.042 *

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 7. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Liver * Fatty Change	Simple Incidence	19/49 (38.8%)	17/50 (34.0%)	17/48 (35.4%)	18/50 (36.0%)	11/50 (22.0%)	15/46 (32.6%)
	Poly-K Incidence	19/38.7 (49.1%)	17/37.7 (45.1%)	17/37.5 (45.3%)	18/38.4 (46.9%)	11/36.8 (29.9%)	15/36.1 (41.5%)
	Terminal Incidence	3/11 (27.3%)	2/12 (16.7%)	2/13 (15.4%)	4/13 (30.8%)	5/17 (29.4%)	4/13 (30.8%)
	Time-to-First	259	397	458	461	520	446
	Poly-K P-Value	0.114N	0.449N	0.459N	0.516N	0.061N	0.328N
	Severity Profile	1 5 1 1 2	3 6 7 1	3 5 7 2	4 9 4 1	2 3 4 2	0 9 5 1
	JT/SW P-Value	0.078N	0.209N	0.297N	0.254N	0.032N* ¹	0.102N
	RTE P-Value	0.084N	0.208N	0.282N	0.204N	0.026N*	0.179N
Liver * Fibrosis,Biliary Tract	Simple Incidence	7/49 (14.3%)	6/50 (12.0%)	8/48 (16.7%)	7/50 (14.0%)	5/50 (10.0%)	8/46 (17.4%)
	Poly-K Incidence	7/32.4 (21.6%)	6/32.4 (18.5%)	8/32.8 (24.4%)	7/35.9 (19.5%)	5/35.8 (14.0%)	8/31.8 (25.2%)
	Terminal Incidence	3/11 (27.3%)	3/12 (25.0%)	3/13 (23.1%)	1/13 (7.7%)	1/17 (5.9%)	4/13 (30.8%)
	Time-to-First	634	537	540	541	646	634
	Poly-K P-Value	0.494N	0.500N	0.511	0.534N	0.304N	0.483
	Severity Profile	6 1 0 0	3 2 1 0	6 2 0 0	7 0 0 0	3 1 1 0	6 2 0 0
	JT/SW P-Value	0.449	0.594	0.427	0.555	0.677	0.433
	RTE P-Value	0.436	0.410N	0.358	0.469N	0.294N	0.323
Liver * Hematopoietic Cell Proliferation	Simple Incidence	3/49 (6.1%)	1/50 (2.0%)	3/48 (6.3%)	2/50 (4.0%)	4/50 (8.0%)	2/46 (4.3%)
	Poly-K Incidence	3/32.9 (9.1%)	1/31.3 (3.2%)	3/32.6 (9.2%)	2/34.7 (5.8%)	4/35.7 (11.2%)	2/32.1 (6.2%)
	Terminal Incidence	0/11 (0.0%)	0/12 (0.0%)	0/13 (0.0%)	1/13 (7.7%)	2/17 (11.8%)	0/13 (0.0%)
	Time-to-First	467	702	461	450	504	463
	Poly-K P-Value	0.473	0.321N	0.661	0.475N	0.545	0.512N
	Severity Profile	3 0 0 0	0 1 0 0	2 1 0 0	2 0 0 0	2 2 0 0	2 0 0 0
	JT/SW P-Value	0.385	0.843	0.561	0.713	0.426	0.625
	RTE P-Value	0.397	0.237N	0.479	0.320N	0.323	0.351N
Liver * Hepatodiaphragmatic Nodule	Simple Incidence	2/49 (4.1%)	5/50 (10.0%)	1/48 (2.1%)	6/50 (12.0%)	3/50 (6.0%)	4/46 (8.7%)
	Poly-K Incidence	2/32.0 (6.3%)	5/32.8 (15.3%)	1/30.5 (3.3%)	6/35.3 (17.0%)	3/36.1 (8.3%)	4/32.2 (12.4%)
	Terminal Incidence	1/11 (9.1%)	1/12 (8.3%)	1/13 (7.7%)	2/13 (15.4%)	1/17 (5.9%)	2/13 (15.4%)
	Time-to-First	492	484	727 (T)	540	141	393
	Poly-K P-Value	0.341	0.220	0.517N	0.160	0.556	0.337
Liver * Hyperplasia,Bile Duct	Simple Incidence	20/49 (40.8%)	11/50 (22.0%)	18/48 (37.5%)	19/50 (38.0%)	18/50 (36.0%)	17/46 (37.0%)
	Poly-K Incidence	20/35.7 (56.0%)	11/32.6 (33.7%)	18/37.3 (48.2%)	19/38.4 (49.4%)	18/39.8 (45.2%)	17/34.4 (49.5%)
	Terminal Incidence	9/11 (81.8%)	7/12 (58.3%)	5/13 (38.5%)	6/13 (46.2%)	6/17 (35.3%)	8/13 (61.5%)
	Time-to-First	259	613	442	448	447	485
	Poly-K P-Value	0.485N	0.039N*	0.321N	0.360N	0.226N	0.369N
	Severity Profile	10 8 1 1	3 5 2 1	7 7 4 0	7 7 5 0	6 9 1 2	8 6 3 0
	JT/SW P-Value	0.324	0.955	0.640	0.627	0.689	0.717
	RTE P-Value	0.327	0.060N	0.452N	0.493N	0.410N	0.386N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 7. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Liver * Infiltration Cellular, Mononuclear Cell	Simple Incidence	29/49 (59.2%)	28/50 (56.0%)	33/48 (68.8%)	25/50 (50.0%)	31/50 (62.0%)	31/46 (67.4%)
	Poly-K Incidence	29/39.7 (73.0%)	28/38.9 (72.0%)	33/41.5 (79.5%)	25/39.8 (62.7%)	31/41.0 (75.6%)	31/37.2 (83.3%)
	Terminal Incidence	9/11 (81.8%)	11/12 (91.7%)	10/13 (76.9%)	9/13 (69.2%)	15/17 (88.2%)	13/13 (100.0%)
	Time-to-First	259	427	442	450	447	462
	Poly-K P-Value	0.215	0.570N	0.313	0.205N	0.496	0.166
	Severity Profile	22 6 1 0	18 10 0 0	26 7 0 0	16 9 0 0	25 5 1 0	23 8 0 0
	JT/SW P-Value	0.328	0.491	0.280	0.583	0.593	0.299
	RTE P-Value	0.320	0.485	0.234	0.294N	0.463	0.222
Liver * Inflammation, Chronic Active	Simple Incidence	2/49 (4.1%)	3/50 (6.0%)	1/48 (2.1%)	3/50 (6.0%)	0/50 (0.0%)	4/46 (8.7%)
	Poly-K Incidence	2/32.0 (6.3%)	3/32.5 (9.2%)	1/30.9 (3.2%)	3/35.1 (8.5%)	0/34.9 (0.0%)	4/33.2 (12.0%)
	Terminal Incidence	1/11 (9.1%)	0/12 (0.0%)	0/13 (0.0%)	0/13 (0.0%)	0/17 (0.0%)	0/13 (0.0%)
	Time-to-First	499	561	608	541	----	445
	Poly-K P-Value	0.460	0.508	0.512N	0.543	0.217N	0.352
	Severity Profile	2 0 0 0	2 1 0 0	0 1 0 0	1 2 0 0	---	1 3 0 0
	JT/SW P-Value	0.371	0.326	0.574	0.397	0.689	0.173
	RTE P-Value	0.343	0.318	0.329N	0.311	0.221N	0.095
Liver * Mineralization	Simple Incidence	1/49 (2.0%)	4/50 (8.0%)	0/48 (0.0%)	1/50 (2.0%)	0/50 (0.0%)	0/46 (0.0%)
	Poly-K Incidence	1/31.6 (3.2%)	4/33.5 (11.9%)	0/30.5 (0.0%)	1/34.6 (2.9%)	0/34.9 (0.0%)	0/30.9 (0.0%)
	Terminal Incidence	0/11 (0.0%)	0/12 (0.0%)	0/13 (0.0%)	0/13 (0.0%)	0/17 (0.0%)	0/13 (0.0%)
	Time-to-First	628	478	----	525	----	----
	Poly-K P-Value	0.028N*	0.192	0.507N	0.742N	0.481N	0.505N
	Severity Profile	1 0 0 0	2 2 0 0	---	0 1 0 0	---	---
	JT/SW P-Value	0.029N*	0.914N	0.350N	0.491N	0.341N	0.330N
	RTE P-Value	0.035N*	0.015 *	0.239N	0.500	0.237N	0.242N
Liver * Mixed Cell Focus	Simple Incidence	1/49 (2.0%)	2/50 (4.0%)	1/48 (2.1%)	1/50 (2.0%)	0/50 (0.0%)	4/46 (8.7%)
	Poly-K Incidence	1/31.8 (3.1%)	2/31.2 (6.4%)	1/30.6 (3.3%)	1/34.0 (2.9%)	0/34.9 (0.0%)	4/32.1 (12.5%)
	Terminal Incidence	0/11 (0.0%)	2/12 (16.7%)	0/13 (0.0%)	0/13 (0.0%)	0/17 (0.0%)	2/13 (15.4%)
	Time-to-First	582	725 (T)	708	707	----	463
	Poly-K P-Value	0.222	0.493	0.754	0.747N	0.482N	0.177
Liver * Tension Lipidosis	Simple Incidence	4/49 (8.2%)	13/50 (26.0%)	5/48 (10.4%)	13/50 (26.0%)	6/50 (12.0%)	10/46 (21.7%)
	Poly-K Incidence	4/32.6 (12.3%)	13/36.2 (35.9%)	5/32.3 (15.5%)	13/39.2 (33.2%)	6/35.8 (16.8%)	10/33.8 (29.6%)
	Terminal Incidence	1/11 (9.1%)	2/12 (16.7%)	1/13 (7.7%)	2/13 (15.4%)	3/17 (17.6%)	4/13 (30.8%)
	Time-to-First	502	484	568	450	642	393
	Poly-K P-Value	0.276	0.019 *	0.493	0.032 *	0.426	0.070
	Severity Profile	1 0 2 1	0 3 4 6	0 2 2 1	0 3 4 6	0 0 1 5	0 1 4 5
	JT/SW P-Value	0.155	0.008 ** ¹	0.090	0.010 * ¹	0.080	0.044 *
	RTE P-Value	0.149	0.008 **	0.396	0.009 **	0.255	0.030 *

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Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 7. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Liver * Vacuolization Cytoplasmic	Simple Incidence	12/49 (24.5%)	19/50 (38.0%)	15/48 (31.3%)	9/50 (18.0%)	16/50 (32.0%)	12/46 (26.1%)
	Poly-K Incidence	12/35.2 (34.1%)	19/36.5 (52.0%)	15/36.1 (41.5%)	9/37.0 (24.3%)	16/38.6 (41.4%)	12/33.3 (36.0%)
	Terminal Incidence	3/11 (27.3%)	8/12 (66.7%)	3/13 (23.1%)	2/13 (15.4%)	7/17 (41.2%)	4/13 (30.8%)
	Time-to-First	468	474	461	450	542	485
	Poly-K P-Value	0.288N	0.083	0.337	0.252N	0.335	0.534
	Severity Profile	6 5 0 1	7 12 0 0	6 9 0 0	3 6 0 0	6 10 0 0	0 11 0 1
	JT/SW P-Value	0.462N	0.932N	0.849N	0.336N	0.689N	0.752N
	RTE P-Value	0.465N	0.064	0.229	0.267N	0.195	0.292
Pancreas * Degeneration,Acinus	Simple Incidence	36/49 (73.5%)	34/49 (69.4%)	34/47 (72.3%)	35/49 (71.4%)	34/49 (69.4%)	34/46 (73.9%)
	Poly-K Incidence	36/43.4 (82.9%)	34/42.3 (80.3%)	34/43.2 (78.6%)	35/45.2 (77.4%)	34/44.7 (76.0%)	34/41.8 (81.4%)
	Terminal Incidence	10/11 (90.9%)	10/12 (83.3%)	9/13 (69.2%)	10/13 (76.9%)	12/17 (70.6%)	11/13 (84.6%)
	Time-to-First	259	397	339	448	390	383
	Poly-K P-Value	0.336N	0.488N	0.401N	0.338N	0.282N	0.546N
	Severity Profile	10 7 11 8	10 10 8 6	20 8 3 3	14 8 9 4	13 12 3 6	8 12 7 7
	JT/SW P-Value	0.398N	0.225N	0.031N* ¹	0.083N	0.099N	0.180N
	RTE P-Value	0.415N	0.225N	0.021N*	0.146N	0.103N	0.455N
Pancreas * Infiltration Cellular,Lymphocyte	Simple Incidence	32/49 (65.3%)	32/49 (65.3%)	27/47 (57.4%)	28/49 (57.1%)	32/49 (65.3%)	30/46 (65.2%)
	Poly-K Incidence	32/42.9 (74.6%)	32/40.7 (78.6%)	27/39.6 (68.2%)	28/42.2 (66.3%)	32/43.9 (73.0%)	30/39.5 (76.0%)
	Terminal Incidence	7/11 (63.6%)	10/12 (83.3%)	9/13 (69.2%)	8/13 (61.5%)	12/17 (70.6%)	10/13 (76.9%)
	Time-to-First	385	397	339	448	390	445
	Poly-K P-Value	0.425N	0.420	0.332N	0.260N	0.531N	0.547
	Severity Profile	12 14 6 0	15 11 6 0	18 8 1 0	15 10 3 0	22 5 5 0	11 17 2 0
	JT/SW P-Value	0.308N	0.386N	0.042N* ¹	0.071N	0.104N	0.179N
	RTE P-Value	0.319N	0.382N	0.035N*	0.086N	0.151N	0.423N
Pancreas * Inflammation,Chronic Active	Simple Incidence	4/49 (8.2%)	1/49 (2.0%)	1/47 (2.1%)	1/49 (2.0%)	2/49 (4.1%)	2/46 (4.3%)
	Poly-K Incidence	4/32.3 (12.4%)	1/31.8 (3.1%)	1/30.7 (3.3%)	1/33.5 (3.0%)	2/34.7 (5.8%)	2/30.9 (6.5%)
	Terminal Incidence	2/11 (18.2%)	0/12 (0.0%)	0/13 (0.0%)	1/13 (7.7%)	1/17 (5.9%)	2/13 (15.4%)
	Time-to-First	502	400	528	728 (T)	686	726 (T)
	Poly-K P-Value	0.288N	0.178N	0.190N	0.163N	0.301N	0.354N
	Severity Profile	0 2 1 1	0 1 0 0	0 1 0 0	1 0 0 0	0 1 1 0	0 2 0 0
	JT/SW P-Value	0.271N	0.083N	0.077N	0.060N	0.088N	0.114N
	RTE P-Value	0.280N	0.041N*	0.051N	0.033N*	0.121N	0.179N
Pancreas * Lipomatosis	Simple Incidence	3/49 (6.1%)	6/49 (12.2%)	7/47 (14.9%)	4/49 (8.2%)	6/49 (12.2%)	6/46 (13.0%)
	Poly-K Incidence	3/32.6 (9.2%)	6/32.3 (18.6%)	7/32.0 (21.9%)	4/34.8 (11.5%)	6/35.6 (16.9%)	6/31.9 (18.8%)
	Terminal Incidence	1/11 (9.1%)	3/12 (25.0%)	2/13 (15.4%)	1/13 (7.7%)	4/17 (23.5%)	3/13 (23.1%)
	Time-to-First	509	561	540	505	496	566
	Poly-K P-Value	0.296	0.229	0.139	0.536	0.282	0.222
	Severity Profile	0 1 1 1	0 3 2 1	0 3 4 0	0 4 0 0	0 3 2 1	0 0 3 3
	JT/SW P-Value	0.208	0.155	0.109	0.247	0.223	0.161
	RTE P-Value	0.211	0.187	0.101	0.412	0.190	0.117

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Table 7. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Pancreas * Pigmentation	Simple Incidence	15/49 (30.6%)	13/49 (26.5%)	6/47 (12.8%)	8/49 (16.3%)	11/49 (22.4%)	8/46 (17.4%)
	Poly-K Incidence	15/38.3 (39.2%)	13/36.1 (36.0%)	6/32.1 (18.7%)	8/35.3 (22.6%)	11/39.5 (27.8%)	8/33.1 (24.2%)
	Terminal Incidence	4/11 (36.4%)	3/12 (25.0%)	3/13 (23.1%)	3/13 (23.1%)	3/17 (17.6%)	4/13 (30.8%)
	Time-to-First	259	400	461	535	390	445
	Poly-K P-Value	0.056N	0.483N	0.047N*	0.093N	0.199N	0.129N
	Severity Profile	14 1 0 0	12 1 0 0	5 1 0 0	6 2 0 0	9 2 0 0	6 2 0 0
	JT/SW P-Value	0.080N	0.332N	0.026N* ¹	0.040N* ¹	0.083N	0.088N
	RTE P-Value	0.084N	0.317N	0.018N*	0.055N	0.184N	0.067N
Cardiovascular System							
Heart * Cardiomyopathy	Simple Incidence	32/50 (64.0%)	37/50 (74.0%)	38/48 (79.2%)	37/50 (74.0%)	35/50 (70.0%)	35/46 (76.1%)
	Poly-K Incidence	32/42.9 (74.5%)	37/42.9 (86.3%)	38/43.1 (88.1%)	37/44.0 (84.2%)	35/44.0 (79.6%)	35/39.7 (88.2%)
	Terminal Incidence	9/11 (81.8%)	11/12 (91.7%)	11/13 (84.6%)	11/13 (84.6%)	15/17 (88.2%)	12/13 (92.3%)
	Time-to-First	259	446	442	450	141	393
	Poly-K P-Value	0.166	0.101	0.062	0.167	0.366	0.064
	Severity Profile	26 3 3 0	22 13 2 0	29 7 2 0	21 14 2 0	17 13 5 0	16 14 5 0
	JT/SW P-Value	0.006 **	0.038 * ¹	0.053	0.030 *	0.029 *	0.004 **
	RTE P-Value	0.007 **	0.043 *	0.092	0.034 *	0.024 *	0.004 **
Endocrine System							
Adrenal Cortex * Angiectasis	Simple Incidence	6/49 (12.2%)	10/49 (20.4%)	8/48 (16.7%)	2/50 (4.0%)	6/50 (12.0%)	10/46 (21.7%)
	Poly-K Incidence	6/33.1 (18.1%)	10/34.5 (29.0%)	8/32.2 (24.8%)	2/34.9 (5.7%)	6/36.0 (16.7%)	10/33.0 (30.3%)
	Terminal Incidence	2/11 (18.2%)	2/12 (16.7%)	3/13 (23.1%)	0/13 (0.0%)	3/17 (17.6%)	5/13 (38.5%)
	Time-to-First	502	474	573	540	506	469
	Poly-K P-Value	0.506	0.217	0.356	0.110N	0.563N	0.186
	Severity Profile	0 3 2 1	0 6 3 1	1 5 1 1	0 2 0 0	0 4 2 0	0 8 1 1
	JT/SW P-Value	0.469	0.148	0.263	0.553	0.597	0.146
	RTE P-Value	0.445	0.125	0.297	0.101N	0.466N	0.115
Adrenal Cortex * Degeneration,Cystic	Simple Incidence	27/49 (55.1%)	28/49 (57.1%)	32/48 (66.7%)	32/50 (64.0%)	33/50 (66.0%)	25/46 (54.3%)
	Poly-K Incidence	27/39.0 (69.3%)	28/39.2 (71.4%)	32/40.4 (79.3%)	32/41.7 (76.7%)	33/41.6 (79.4%)	25/36.7 (68.0%)
	Terminal Incidence	8/11 (72.7%)	8/12 (66.7%)	10/13 (76.9%)	10/13 (76.9%)	15/17 (88.2%)	8/13 (61.5%)
	Time-to-First	492	484	442	450	506	469
	Poly-K P-Value	0.383	0.521	0.194	0.289	0.186	0.556N
	Severity Profile	4 7 4 12	4 15 3 6	3 12 7 10	5 8 5 14	2 11 10 10	3 12 5 5
	JT/SW P-Value	0.396	0.695	0.236	0.264	0.236	0.426
	RTE P-Value	0.423	0.263N	0.208	0.206	0.164	0.240N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 7. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Adrenal Cortex * Hyperplasia	Simple Incidence	3/49 (6.1%)	5/49 (10.2%)	4/48 (8.3%)	7/50 (14.0%)	3/50 (6.0%)	7/46 (15.2%)
	Poly-K Incidence	3/31.8 (9.4%)	5/32.2 (15.5%)	4/31.6 (12.7%)	7/35.2 (19.9%)	3/35.8 (8.4%)	7/32.6 (21.5%)
	Terminal Incidence	0/11 (0.0%)	2/12 (16.7%)	0/13 (0.0%)	3/13 (23.1%)	1/17 (5.9%)	3/13 (23.1%)
	Time-to-First	628	563	540	540	496	558
	Poly-K P-Value	0.216	0.358	0.496	0.193	0.609N	0.157
	Severity Profile	1 2 0 0	1 2 1 1	4 0 0 0	2 5 0 0	0 2 1 0	4 2 0 1
	JT/SW P-Value	0.154	0.218	0.345	0.115	0.322	0.097
	RTE P-Value	0.146	0.233	0.388	0.095	0.490	0.077
Adrenal Cortex * Hypertrophy	Simple Incidence	1/49 (2.0%)	0/49 (0.0%)	1/48 (2.1%)	2/50 (4.0%)	0/50 (0.0%)	4/46 (8.7%)
	Poly-K Incidence	1/32.0 (3.1%)	0/31.0 (0.0%)	1/31.3 (3.2%)	2/34.2 (5.8%)	0/34.9 (0.0%)	4/31.0 (12.9%)
	Terminal Incidence	0/11 (0.0%)	0/12 (0.0%)	0/13 (0.0%)	0/13 (0.0%)	0/17 (0.0%)	3/13 (23.1%)
	Time-to-First	499	----	442	690	----	702
	Poly-K P-Value	0.062	0.506N	0.758	0.524	0.483N	0.164
	Severity Profile	1 0 0 0	---	1 0 0 0	0 1 1 0	---	0 2 2 0
	JT/SW P-Value	0.042 *	0.841	0.576	0.306	0.635	0.027 *
	RTE P-Value	0.032 *	0.271N	0.495	0.184	0.270N	0.011 *
Adrenal Cortex * Vacuolization Cytoplasmic	Simple Incidence	4/49 (8.2%)	3/49 (6.1%)	3/48 (6.3%)	6/50 (12.0%)	5/50 (10.0%)	6/46 (13.0%)
	Poly-K Incidence	4/32.3 (12.4%)	3/31.9 (9.4%)	3/31.7 (9.5%)	6/36.1 (16.6%)	5/35.8 (14.0%)	6/33.0 (18.2%)
	Terminal Incidence	2/11 (18.2%)	0/12 (0.0%)	0/13 (0.0%)	1/13 (7.7%)	2/17 (11.8%)	1/13 (7.7%)
	Time-to-First	468	537	540	461	630	446
	Poly-K P-Value	0.172	0.506N	0.510N	0.440	0.567	0.379
	Severity Profile	2 0 1 1	0 2 1 0	1 1 1 0	0 6 0 0	2 3 0 0	1 3 1 1
	JT/SW P-Value	0.122	0.649	0.736	0.316	0.416	0.270
	RTE P-Value	0.120	0.372N	0.372N	0.258	0.397	0.189
Adrenal Medulla * Hyperplasia	Simple Incidence	7/49 (14.3%)	5/50 (10.0%)	4/48 (8.3%)	8/48 (16.7%)	8/50 (16.0%)	5/45 (11.1%)
	Poly-K Incidence	7/32.0 (21.9%)	5/31.4 (15.9%)	4/30.9 (12.9%)	8/34.6 (23.1%)	8/36.0 (22.2%)	5/31.2 (16.0%)
	Terminal Incidence	4/11 (36.4%)	4/12 (33.3%)	2/13 (15.4%)	2/13 (15.4%)	5/17 (29.4%)	2/13 (15.4%)
	Time-to-First	533	660	644	541	504	650
	Poly-K P-Value	0.511	0.386N	0.270N	0.569	0.604	0.392N
	Severity Profile	5 2 0 0	3 1 1 0	1 2 1 0	5 3 0 0	6 2 0 0	2 2 1 0
	JT/SW P-Value	0.380	0.730	0.847	0.449	0.497	0.610
	RTE P-Value	0.388	0.279N	0.220N	0.357	0.406	0.355N
Parathyroid Gland * Hyperplasia	Simple Incidence	5/45 (11.1%)	3/49 (6.1%)	8/47 (17.0%)	7/47 (14.9%)	5/47 (10.6%)	7/46 (15.2%)
	Poly-K Incidence	5/31.0 (16.1%)	3/31.9 (9.4%)	8/32.7 (24.4%)	7/34.3 (20.4%)	5/33.7 (14.8%)	7/33.0 (21.2%)
	Terminal Incidence	1/11 (9.1%)	0/12 (0.0%)	2/13 (15.4%)	0/12 (0.0%)	3/16 (18.8%)	3/13 (23.1%)
	Time-to-First	259	573	528	485	496	383
	Poly-K P-Value	0.282	0.336N	0.301	0.449	0.580N	0.420
	Severity Profile	3 0 1 1	1 2 0 0	5 3 0 0	3 4 0 0	0 3 1 1	5 2 0 0
	JT/SW P-Value	0.210	0.805	0.240	0.319	0.428	0.411
	RTE P-Value	0.220	0.234N	0.216	0.297	0.487	0.306

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 7. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Pituitary Gland * Angiectasis	Simple Incidence	12/49 (24.5%)	11/50 (22.0%)	8/48 (16.7%)	12/50 (24.0%)	14/50 (28.0%)	11/46 (23.9%)
	Poly-K Incidence	12/35.3 (34.0%)	11/34.5 (31.8%)	8/32.7 (24.4%)	12/38.4 (31.3%)	14/37.6 (37.2%)	11/33.9 (32.5%)
	Terminal Incidence	4/11 (36.4%)	4/12 (33.3%)	4/13 (30.8%)	2/13 (15.4%)	7/17 (41.2%)	4/13 (30.8%)
	Time-to-First	502	397	488	448	520	445
	Poly-K P-Value	0.419	0.526N	0.269N	0.500N	0.482	0.550N
	Severity Profile	0 0 0 12	0 0 1 10	0 1 2 5	0 3 1 8	0 1 2 11	0 2 5 4
	JT/SW P-Value	0.465	0.636	0.846	0.733	0.512	0.684
	RTE P-Value	0.475	0.361N	0.134N	0.383N	0.392	0.323N
Pituitary Gland * Cyst,Pars Distalis	Simple Incidence	4/49 (8.2%)	6/50 (12.0%)	10/48 (20.8%)	3/50 (6.0%)	5/50 (10.0%)	4/46 (8.7%)
	Poly-K Incidence	4/33.2 (12.0%)	6/32.8 (18.3%)	10/34.9 (28.6%)	3/35.5 (8.5%)	5/36.1 (13.9%)	4/32.6 (12.3%)
	Terminal Incidence	1/11 (9.1%)	2/12 (16.7%)	1/13 (7.7%)	0/13 (0.0%)	2/17 (11.8%)	1/13 (7.7%)
	Time-to-First	519	474	461	461	470	446
	Poly-K P-Value	0.271N	0.357	0.076	0.464N	0.553	0.636
	Pituitary Gland * Hyperplasia,Pars Distalis	Simple Incidence	25/49 (51.0%)	32/50 (64.0%)	34/48 (70.8%)	26/50 (52.0%)	28/50 (56.0%)
Poly-K Incidence		25/42.2 (59.2%)	32/43.5 (73.5%)	34/45.0 (75.5%)	26/43.3 (60.1%)	28/45.3 (61.8%)	21/39.1 (53.7%)
Terminal Incidence		4/11 (36.4%)	7/12 (58.3%)	5/13 (38.5%)	6/13 (46.2%)	7/17 (41.2%)	6/13 (46.2%)
Time-to-First		385	400	339	461	390	383
Poly-K P-Value		0.099N	0.104	0.069	0.560	0.490	0.385N
Severity Profile		3 7 7 8	0 5 11 16	2 6 14 12	0 6 9 11	3 7 5 13	1 3 7 10
JT/SW P-Value		0.231N	0.979N	0.995N	0.851N	0.884N	0.704N
RTE P-Value		0.224N	0.023 *	0.020 *	0.272	0.213	0.448
Thyroid Gland * Hyperplasia,C-Cell	Simple Incidence	26/48 (54.2%)	29/49 (59.2%)	17/45 (37.8%)	23/48 (47.9%)	28/50 (56.0%)	24/46 (52.2%)
	Poly-K Incidence	26/40.5 (64.2%)	29/42.0 (69.0%)	17/34.9 (48.8%)	23/39.8 (57.8%)	28/42.6 (65.7%)	24/38.9 (61.7%)
	Terminal Incidence	7/11 (63.6%)	7/12 (58.3%)	4/13 (30.8%)	6/13 (46.2%)	9/17 (52.9%)	6/13 (46.2%)
	Time-to-First	259	397	505	448	504	383
	Poly-K P-Value	0.410N	0.403	0.117N	0.352N	0.536	0.502N
	Severity Profile	8 15 2 1	15 11 1 2	11 5 0 1	15 7 1 0	10 12 4 2	11 11 2 0
	JT/SW P-Value	0.403N	0.462N	0.017N* ¹	0.043N* ¹	0.180N	0.230N
	RTE P-Value	0.408N	0.487N	0.017N*	0.079N	0.420	0.284N
Thyroid Gland * Hyperplasia,Follicular Cell	Simple Incidence	4/48 (8.3%)	4/49 (8.2%)	7/45 (15.6%)	6/48 (12.5%)	5/50 (10.0%)	4/46 (8.7%)
	Poly-K Incidence	4/32.8 (12.2%)	4/32.0 (12.5%)	7/31.6 (22.2%)	6/35.4 (17.0%)	5/35.9 (13.9%)	4/33.2 (12.1%)
	Terminal Incidence	0/11 (0.0%)	1/12 (8.3%)	1/13 (7.7%)	0/13 (0.0%)	2/17 (11.8%)	0/13 (0.0%)
	Time-to-First	519	622	540	450	520	383
	Poly-K P-Value	0.501N	0.634	0.229	0.415	0.558	0.641N
	Severity Profile	0 2 2 0	1 3 0 0	0 5 2 0	0 4 2 0	0 3 2 0	0 3 1 0
	JT/SW P-Value	0.439	0.542	0.160	0.250	0.339	0.416
	RTE P-Value	0.449	0.453N	0.147	0.261	0.399	0.491

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 7. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Thyroid Gland * Ultimobranchial Cyst	Simple Incidence	2/48 (4.2%)	7/49 (14.3%)	2/45 (4.4%)	9/48 (18.8%)	11/50 (22.0%)	3/46 (6.5%)
	Poly-K Incidence	2/31.4 (6.4%)	7/33.4 (21.0%)	2/29.5 (6.8%)	9/36.1 (24.9%)	11/38.6 (28.5%)	3/32.1 (9.3%)
	Terminal Incidence	0/11 (0.0%)	2/12 (16.7%)	1/13 (7.7%)	2/13 (15.4%)	4/17 (23.5%)	1/13 (7.7%)
	Time-to-First	602	446	651	448	141	446
	Poly-K P-Value	0.140	0.085	0.673	0.038 *	0.017 *	0.510
Genital System							
Ovary * Atrophy	Simple Incidence	47/49 (95.9%)	48/49 (98.0%)	46/47 (97.9%)	50/50 (100.0%)	49/50 (98.0%)	44/46 (95.7%)
	Poly-K Incidence	47/47.5 (98.9%)	48/48.1 (99.8%)	46/46.1 (99.8%)	50/50.0 (100.0%)	49/49.0 (100.0%)	44/44.8 (98.2%)
	Terminal Incidence	11/11 (100.0%)	12/12 (100.0%)	13/13 (100.0%)	13/13 (100.0%)	17/17 (100.0%)	13/13 (100.0%)
	Time-to-First	259	397	442	448	390	383
	Poly-K P-Value	0.469N	0.922	0.927	0.885	0.890	0.800N
	Severity Profile	1 23 16 7	0 34 11 3	1 28 11 6	1 33 7 9	0 25 16 8	0 23 12 9
	JT/SW P-Value	0.134	0.942	0.867	0.895	0.455	0.514
RTE P-Value	0.132	0.064N	0.216N	0.213N	0.349	0.423	
Ovary * Cyst	Simple Incidence	6/49 (12.2%)	8/49 (16.3%)	5/47 (10.6%)	9/50 (18.0%)	5/50 (10.0%)	6/46 (13.0%)
	Poly-K Incidence	6/32.1 (18.7%)	8/33.8 (23.7%)	5/31.5 (15.9%)	9/36.1 (24.9%)	5/35.5 (14.1%)	6/31.7 (18.9%)
	Terminal Incidence	2/11 (18.2%)	1/12 (8.3%)	1/13 (7.7%)	3/13 (23.1%)	4/17 (23.5%)	2/13 (15.4%)
	Time-to-First	573	397	581	497	496	634
	Poly-K P-Value	0.379N	0.423	0.515N	0.370	0.426N	0.619
Ovary * Cyst,Follicle	Simple Incidence	4/49 (8.2%)	4/49 (8.2%)	2/47 (4.3%)	1/50 (2.0%)	2/50 (4.0%)	4/46 (8.7%)
	Poly-K Incidence	4/32.0 (12.5%)	4/33.5 (11.9%)	2/30.2 (6.6%)	1/34.6 (2.9%)	2/35.7 (5.6%)	4/32.4 (12.3%)
	Terminal Incidence	2/11 (18.2%)	0/12 (0.0%)	2/13 (15.4%)	0/13 (0.0%)	0/17 (0.0%)	1/13 (7.7%)
	Time-to-First	582	400	724 (T)	505	568	383
	Poly-K P-Value	0.306N	0.622N	0.361N	0.152N	0.285N	0.641N
Ovary * Hyperplasia,Sertoliform	Simple Incidence	6/49 (12.2%)	4/49 (8.2%)	5/47 (10.6%)	6/50 (12.0%)	7/50 (14.0%)	6/46 (13.0%)
	Poly-K Incidence	6/32.0 (18.8%)	4/31.2 (12.8%)	5/31.4 (15.9%)	6/34.6 (17.3%)	7/35.9 (19.5%)	6/32.7 (18.4%)
	Terminal Incidence	3/11 (27.3%)	3/12 (25.0%)	3/13 (23.1%)	4/13 (30.8%)	5/17 (29.4%)	1/13 (7.7%)
	Time-to-First	602	660	461	609	390	513
	Poly-K P-Value	0.381	0.378N	0.513N	0.567N	0.594	0.610N
	Severity Profile	1 1 2 2	2 1 1 0	2 3 0 0	3 3 0 0	5 2 0 0	3 1 2 0
	JT/SW P-Value	0.322	0.774	0.734	0.695	0.598	0.627
	RTE P-Value	0.325	0.231N	0.358N	0.429N	0.468	0.494

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 7. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Uterus * Atrophy	Simple Incidence	10/49 (20.4%)	6/49 (12.2%)	4/48 (8.3%)	7/49 (14.3%)	7/49 (14.3%)	9/46 (19.6%)
	Poly-K Incidence	10/32.8 (30.5%)	6/32.6 (18.4%)	4/32.0 (12.5%)	7/34.0 (20.6%)	7/35.4 (19.8%)	9/33.3 (27.0%)
	Terminal Incidence	5/11 (45.5%)	2/12 (16.7%)	1/13 (7.7%)	6/13 (46.2%)	4/17 (23.5%)	2/13 (15.4%)
	Time-to-First	502	561	539	602	630	558
	Poly-K P-Value	0.497N	0.192N	0.066N	0.254N	0.224N	0.483N
	Severity Profile	0 0 7 3	0 0 5 1	0 0 4 0	0 0 6 1	0 0 6 1	0 0 8 1
	JT/SW P-Value	0.467	0.870	0.970	0.916	0.928	0.730
	RTE P-Value	0.454	0.106N	0.033N*	0.167N	0.166N	0.424N
Uterus * Dilatation,Lumen	Simple Incidence	3/49 (6.1%)	6/49 (12.2%)	2/48 (4.2%)	4/49 (8.2%)	2/49 (4.1%)	0/46 (0.0%)
	Poly-K Incidence	3/32.5 (9.2%)	6/33.0 (18.2%)	2/31.3 (6.4%)	4/33.8 (11.8%)	2/35.2 (5.7%)	0/30.9 (0.0%)
	Terminal Incidence	0/11 (0.0%)	2/12 (16.7%)	1/13 (7.7%)	3/13 (23.1%)	1/17 (5.9%)	0/13 (0.0%)
	Time-to-First	522	484	442	672	496	----
	Poly-K P-Value	0.034N*	0.242	0.518N	0.521	0.463N	0.125N
	Severity Profile	0 0 1 2	0 0 0 6	0 0 0 2	0 0 0 4	0 0 1 1	---
	JT/SW P-Value	0.038N*	0.861N	0.436N	0.635N	0.453N	0.140N
	RTE P-Value	0.033N*	0.069	0.349N	0.323	0.332N	0.084N
Uterus * Hyperplasia,Cystic,Endometrium	Simple Incidence	18/49 (36.7%)	23/49 (46.9%)	22/48 (45.8%)	25/49 (51.0%)	28/49 (57.1%)	24/46 (52.2%)
	Poly-K Incidence	18/38.3 (47.0%)	23/38.1 (60.4%)	22/37.1 (59.2%)	25/41.6 (60.0%)	28/42.5 (65.8%)	24/38.6 (62.2%)
	Terminal Incidence	4/11 (36.4%)	7/12 (58.3%)	7/13 (53.8%)	6/13 (46.2%)	9/17 (52.9%)	7/13 (53.8%)
	Time-to-First	468	446	446	461	447	383
	Poly-K P-Value	0.071	0.157	0.188	0.161	0.058	0.119
	Severity Profile	3 8 5 2	1 18 4 0	1 15 5 1	3 15 6 1	0 18 6 4	4 11 6 3
	JT/SW P-Value	0.019 *	0.218	0.242	0.140	0.017 *	0.045 *
	RTE P-Value	0.023 *	0.244	0.215	0.124	0.014 *	0.080
Uterus * Hyperplasia,Endometrium	Simple Incidence	18/49 (36.7%)	14/49 (28.6%)	17/48 (35.4%)	14/49 (28.6%)	12/49 (24.5%)	10/46 (21.7%)
	Poly-K Incidence	18/38.8 (46.4%)	14/37.4 (37.5%)	17/37.0 (46.0%)	14/39.2 (35.7%)	12/38.5 (31.2%)	10/33.6 (29.7%)
	Terminal Incidence	3/11 (27.3%)	2/12 (16.7%)	4/13 (30.8%)	1/13 (7.7%)	4/17 (23.5%)	5/13 (38.5%)
	Time-to-First	259	397	461	448	390	446
	Poly-K P-Value	0.044N*	0.281N	0.580N	0.225N	0.118N	0.103N
	Severity Profile	6 12 0 0	8 6 0 0	7 9 0 1	6 7 1 0	2 10 0 0	1 8 1 0
	JT/SW P-Value	0.087N	0.136N	0.312N	0.230N	0.157N	0.109N
	RTE P-Value	0.093N	0.140N	0.429N	0.182N	0.122N	0.089N
Uterus * Metaplasia,Squamous	Simple Incidence	5/49 (10.2%)	1/49 (2.0%)	2/48 (4.2%)	2/49 (4.1%)	4/49 (8.2%)	3/46 (6.5%)
	Poly-K Incidence	5/33.1 (15.1%)	1/31.7 (3.2%)	2/30.8 (6.5%)	2/34.8 (5.8%)	4/36.2 (11.1%)	3/32.6 (9.2%)
	Terminal Incidence	1/11 (9.1%)	0/12 (0.0%)	1/13 (7.7%)	0/13 (0.0%)	1/17 (5.9%)	0/13 (0.0%)
	Time-to-First	502	474	651	497	447	383
	Poly-K P-Value	0.466N	0.106N	0.240N	0.191N	0.444N	0.361N
	Severity Profile	3 2 0 0	1 0 0 0	1 1 0 0	0 2 0 0	3 1 0 0	3 0 0 0
	JT/SW P-Value	0.483N	0.045N* '1	0.073N	0.083N	0.155N	0.186N
	RTE P-Value	0.488N	0.045N*	0.119N	0.129N	0.328N	0.214N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 7. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Vagina * Degeneration,Epithelium	Simple Incidence	5/49 (10.2%)	4/50 (8.0%)	5/47 (10.6%)	2/49 (4.1%)	5/49 (10.2%)	3/46 (6.5%)
	Poly-K Incidence	5/32.9 (15.2%)	4/32.8 (12.2%)	5/31.4 (15.9%)	2/33.4 (6.0%)	5/36.2 (13.8%)	3/31.9 (9.4%)
	Terminal Incidence	2/11 (18.2%)	1/12 (8.3%)	2/13 (15.4%)	1/13 (7.7%)	2/17 (11.8%)	1/13 (7.7%)
	Time-to-First	495	446	600	707	390	566
	Poly-K P-Value	0.271N	0.503N	0.605	0.204N	0.572N	0.370N
	Severity Profile	0 1 2 2	0 2 1 1	0 2 1 2	0 0 2 0	0 1 2 2	0 0 3 0
	JT/SW P-Value	0.296N	0.337N	0.503N	0.167N	0.386N	0.340N
	RTE P-Value	0.293N	0.331N	0.478	0.130N	0.500	0.253N
Vagina * Hyperplasia,Epithelium	Simple Incidence	6/49 (12.2%)	10/50 (20.0%)	3/47 (6.4%)	7/49 (14.3%)	7/49 (14.3%)	7/46 (15.2%)
	Poly-K Incidence	6/33.7 (17.8%)	10/35.4 (28.3%)	3/31.8 (9.4%)	7/35.9 (19.5%)	7/37.6 (18.6%)	7/34.6 (20.2%)
	Terminal Incidence	0/11 (0.0%)	3/12 (25.0%)	1/13 (7.7%)	2/13 (15.4%)	1/17 (5.9%)	1/13 (7.7%)
	Time-to-First	492	446	442	461	390	383
	Poly-K P-Value	0.459N	0.224	0.264N	0.551	0.587	0.523
	Severity Profile	0 3 2 1	0 5 4 1	0 1 1 1	0 2 4 1	0 1 5 1	0 0 5 2
	JT/SW P-Value	0.391	0.152	0.508	0.465	0.467	0.391
	RTE P-Value	0.380	0.149	0.219N	0.371	0.359	0.290
Vagina * Infiltration Cellular,Polymorphonuclear	Simple Incidence	8/49 (16.3%)	4/50 (8.0%)	6/47 (12.8%)	3/49 (6.1%)	13/49 (26.5%)	8/46 (17.4%)
	Poly-K Incidence	8/34.6 (23.1%)	4/32.9 (12.2%)	6/32.0 (18.8%)	3/34.2 (8.8%)	13/38.1 (34.2%)	8/33.6 (23.8%)
	Terminal Incidence	1/11 (9.1%)	1/12 (8.3%)	2/13 (15.4%)	1/13 (7.7%)	6/17 (35.3%)	2/13 (15.4%)
	Time-to-First	467	446	570	540	504	446
	Poly-K P-Value	0.136	0.192N	0.446N	0.094N	0.212	0.588
	Severity Profile	1 3 2 2	0 1 2 1	0 2 1 3	0 0 3 0	1 7 3 2	0 3 2 3
	JT/SW P-Value	0.102	0.888	0.760	0.934	0.109	0.291
	RTE P-Value	0.103	0.130N	0.341N	0.085N	0.090	0.413
Vagina * Mucification,Epithelium	Simple Incidence	40/49 (81.6%)	46/50 (92.0%)	37/47 (78.7%)	44/49 (89.8%)	39/49 (79.6%)	34/46 (73.9%)
	Poly-K Incidence	40/45.8 (87.3%)	46/48.1 (95.6%)	37/42.4 (87.2%)	44/47.9 (91.9%)	39/44.6 (87.5%)	34/39.7 (85.6%)
	Terminal Incidence	8/11 (72.7%)	11/12 (91.7%)	11/13 (84.6%)	11/13 (84.6%)	15/17 (88.2%)	12/13 (92.3%)
	Time-to-First	467	339	458	448	470	445
	Poly-K P-Value	0.236N	0.119	0.634N	0.339	0.624	0.541N
	Severity Profile	0 7 12 21	1 7 15 23	0 9 9 19	2 12 12 18	0 8 9 22	1 5 11 17
	JT/SW P-Value	0.123N	0.782N	0.362N	0.406N	0.482N	0.267N
	RTE P-Value	0.127N	0.211	0.305N	0.355N	0.462N	0.198N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 7. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Hematopoietic System							
Spleen * Hematopoietic Cell Proliferation	Simple Incidence	32/49 (65.3%)	33/50 (66.0%)	29/47 (61.7%)	35/49 (71.4%)	31/49 (63.3%)	32/46 (69.6%)
	Poly-K Incidence	32/42.7 (75.0%)	33/42.6 (77.4%)	29/40.3 (72.0%)	35/44.8 (78.2%)	31/43.5 (71.3%)	32/40.8 (78.4%)
	Terminal Incidence	8/11 (72.7%)	8/12 (66.7%)	9/13 (69.2%)	7/13 (53.8%)	10/17 (58.8%)	9/13 (69.2%)
	Time-to-First	259	446	442	450	447	383
	Poly-K P-Value	0.483	0.497	0.474N	0.457	0.441N	0.450
	Severity Profile	3 10 14 5	3 12 14 4	5 14 5 5	4 13 13 5	2 14 8 7	5 15 7 5
	JT/SW P-Value	0.428N	0.439N	0.167N	0.431N	0.465N	0.475N
	RTE P-Value	0.430N	0.448N	0.144N	0.397	0.380N	0.355N
Spleen * Pigmentation	Simple Incidence	31/49 (63.3%)	34/50 (68.0%)	38/47 (80.9%)	35/49 (71.4%)	32/49 (65.3%)	32/46 (69.6%)
	Poly-K Incidence	31/41.4 (74.9%)	34/43.2 (78.7%)	38/43.3 (87.7%)	35/44.8 (78.1%)	32/43.7 (73.3%)	32/40.7 (78.5%)
	Terminal Incidence	8/11 (72.7%)	10/12 (83.3%)	11/13 (84.6%)	10/13 (76.9%)	11/17 (64.7%)	10/13 (76.9%)
	Time-to-First	385	397	339	448	141	383
	Poly-K P-Value	0.433N	0.431	0.079	0.460	0.533N	0.444
	Severity Profile	5 18 5 3	11 13 3 7	7 21 5 5	8 16 7 4	5 12 10 5	8 12 9 3
	JT/SW P-Value	0.232	0.432	0.071	0.166	0.206	0.248
	RTE P-Value	0.248	0.419	0.069	0.243	0.207	0.273
Thymus * Atrophy	Simple Incidence	48/49 (98.0%)	48/50 (96.0%)	47/48 (97.9%)	47/50 (94.0%)	47/49 (95.9%)	42/46 (91.3%)
	Poly-K Incidence	48/48.7 (98.6%)	48/48.8 (98.3%)	47/47.5 (99.0%)	47/49.6 (94.7%)	47/48.2 (97.6%)	42/43.6 (96.4%)
	Terminal Incidence	11/11 (100.0%)	12/12 (100.0%)	13/13 (100.0%)	11/13 (84.6%)	16/17 (94.1%)	13/13 (100.0%)
	Time-to-First	259	397	339	448	447	393
	Poly-K P-Value	0.173N	0.808N	0.841	0.285N	0.660N	0.489N
	Severity Profile	0 2 9 37	0 1 7 40	0 0 4 43	1 0 6 40	0 0 3 44	0 0 4 38
	JT/SW P-Value	0.135	0.313	0.044 * ¹	0.173	0.046 * ¹	0.135
	RTE P-Value	0.145	0.294	0.038 *	0.312	0.039 *	0.222
Integumentary System							
Mammary Gland * Atypical Focus	Simple Incidence	6/50 (12.0%)	2/50 (4.0%)	6/48 (12.5%)	8/49 (16.3%)	7/50 (14.0%)	5/46 (10.9%)
	Poly-K Incidence	6/33.0 (18.2%)	2/32.0 (6.2%)	6/32.4 (18.5%)	8/36.2 (22.1%)	7/35.8 (19.6%)	5/32.6 (15.3%)
	Terminal Incidence	3/11 (27.3%)	0/12 (0.0%)	3/13 (23.1%)	2/13 (15.4%)	4/17 (23.5%)	2/13 (15.4%)
	Time-to-First	629	593	483	448	582	446
	Poly-K P-Value	0.321	0.134N	0.614	0.458	0.566	0.507N
	Severity Profile	1 4 1 0	0 1 1 0	1 5 0 0	3 4 1 0	0 5 0 2	2 3 0 0
	JT/SW P-Value	0.233	0.924	0.559	0.340	0.410	0.529
	RTE P-Value	0.244	0.117N	0.480	0.271	0.352	0.407N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 7. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Mammary Gland * Dilatation,Alveolus	Simple Incidence	8/50 (16.0%)	4/50 (8.0%)	4/48 (8.3%)	8/49 (16.3%)	3/50 (6.0%)	7/46 (15.2%)
	Poly-K Incidence	8/34.8 (23.0%)	4/33.7 (11.9%)	4/30.5 (13.1%)	8/34.9 (22.9%)	3/35.7 (8.4%)	7/34.9 (20.1%)
	Terminal Incidence	3/11 (27.3%)	0/12 (0.0%)	4/13 (30.8%)	3/13 (23.1%)	1/17 (5.9%)	0/13 (0.0%)
	Time-to-First	492	397	724 (T)	541	563	383
	Poly-K P-Value	0.402N	0.182N	0.235N	0.611N	0.082N	0.498N
	Severity Profile	0 4 4 0	0 4 0 0	0 2 2 0	0 6 2 0	1 2 0 0	1 6 0 0
	JT/SW P-Value	0.401N	0.093N	0.116N	0.256N	0.055N	0.216N
	RTE P-Value	0.420N	0.085N	0.110N	0.493N	0.046N*	0.390N
Mammary Gland * Dilatation,Duct	Simple Incidence	16/50 (32.0%)	5/50 (10.0%)	9/48 (18.8%)	9/49 (18.4%)	7/50 (14.0%)	11/46 (23.9%)
	Poly-K Incidence	16/37.0 (43.3%)	5/34.5 (14.5%)	9/33.7 (26.7%)	9/35.3 (25.5%)	7/36.4 (19.2%)	11/36.2 (30.4%)
	Terminal Incidence	5/11 (45.5%)	0/12 (0.0%)	3/13 (23.1%)	3/13 (23.1%)	2/17 (11.8%)	1/13 (7.7%)
	Time-to-First	492	397	442	541	563	383
	Poly-K P-Value	0.186N	0.005N**	0.104N	0.081N	0.019N*	0.174N
	Severity Profile	0 9 4 3	0 5 0 0	2 4 2 1	0 6 3 0	0 6 1 0	0 7 4 0
	JT/SW P-Value	0.228N	0.002N**	0.011N*	0.017N*	0.008N**	0.027N*
	RTE P-Value	0.249N	0.001N**	0.032N*	0.033N*	0.006N**	0.135N
Mammary Gland * Hyperplasia,Lobular	Simple Incidence	41/50 (82.0%)	40/50 (80.0%)	39/48 (81.3%)	39/49 (79.6%)	36/50 (72.0%)	38/46 (82.6%)
	Poly-K Incidence	41/45.5 (90.1%)	40/46.1 (86.8%)	39/42.7 (91.2%)	39/45.0 (86.7%)	36/45.4 (79.3%)	38/41.6 (91.4%)
	Terminal Incidence	9/11 (81.8%)	9/12 (75.0%)	13/13 (100.0%)	10/13 (76.9%)	12/17 (70.6%)	12/13 (92.3%)
	Time-to-First	467	397	458	448	470	383
	Poly-K P-Value	0.291N	0.421N	0.589	0.419N	0.105N	0.575
	Severity Profile	1 8 15 17	0 8 12 20	3 14 11 11	2 9 13 15	3 5 7 21	2 10 9 17
	JT/SW P-Value	0.357N	0.621N	0.091N	0.201N	0.297N	0.370N
	RTE P-Value	0.378N	0.396	0.088N	0.287N	0.353N	0.443N
Nervous System							
Brain, Brain Stem * Compression	Simple Incidence	15/49 (30.6%)	14/50 (28.0%)	11/48 (22.9%)	11/50 (22.0%)	17/50 (34.0%)	14/46 (30.4%)
	Poly-K Incidence	15/34.3 (43.7%)	14/36.4 (38.5%)	11/33.4 (33.0%)	11/37.5 (29.4%)	17/38.2 (44.5%)	14/34.6 (40.4%)
	Terminal Incidence	6/11 (54.5%)	4/12 (33.3%)	6/13 (46.2%)	1/13 (7.7%)	7/17 (41.2%)	4/13 (30.8%)
	Time-to-First	502	339	442	450	520	445
	Poly-K P-Value	0.512	0.415N	0.243N	0.144N	0.571	0.486N
	Severity Profile	2 7 2 4	2 4 5 3	3 4 2 2	4 1 4 2	5 5 3 4	2 3 7 2
	JT/SW P-Value	0.390	0.583	0.800	0.875	0.509	0.573
	RTE P-Value	0.389	0.410N	0.179N	0.163N	0.391	0.481

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 7. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Brain, Cerebrum * Dilatation, Ventricle	Simple Incidence	5/49 (10.2%)	5/50 (10.0%)	3/48 (6.3%)	2/50 (4.0%)	5/50 (10.0%)	6/46 (13.0%)
	Poly-K Incidence	5/32.3 (15.5%)	5/33.5 (14.9%)	3/32.0 (9.4%)	2/34.9 (5.7%)	5/36.4 (13.7%)	6/33.2 (18.1%)
	Terminal Incidence	1/11 (9.1%)	1/12 (8.3%)	0/13 (0.0%)	0/13 (0.0%)	0/17 (0.0%)	1/13 (7.7%)
	Time-to-First	602	397	510	541	590	445
	Poly-K P-Value	0.462	0.612N	0.358N	0.181N	0.556N	0.519
	Severity Profile	2 3 0 0	4 1 0 0	1 2 0 0	1 0 1 0	2 3 0 0	3 3 0 0
	JT/SW P-Value	0.374	0.540	0.737	0.857	0.653	0.430
	RTE P-Value	0.359	0.462N	0.249N	0.149N	0.486N	0.320
Urinary System							
Kidney * Casts Protein	Simple Incidence	5/49 (10.2%)	5/50 (10.0%)	5/47 (10.6%)	7/49 (14.3%)	5/50 (10.0%)	4/46 (8.7%)
	Poly-K Incidence	5/33.3 (15.0%)	5/32.4 (15.4%)	5/31.3 (16.0%)	7/37.1 (18.9%)	5/35.7 (14.0%)	4/31.8 (12.6%)
	Terminal Incidence	2/11 (18.2%)	1/12 (8.3%)	2/13 (15.4%)	1/13 (7.7%)	2/17 (11.8%)	3/13 (23.1%)
	Time-to-First	495	537	570	461	630	383
	Poly-K P-Value	0.428N	0.617	0.594	0.455	0.589N	0.531N
	Severity Profile	4 1 0 0	4 1 0 0	5 0 0 0	4 2 0 1	3 2 0 0	3 1 0 0
	JT/SW P-Value	0.481N	0.487N	0.583N	0.715N	0.637N	0.543N
	RTE P-Value	0.474N	0.487N	0.487	0.240	0.500	0.410N
Kidney * Cyst, Cortex	Simple Incidence	7/49 (14.3%)	10/50 (20.0%)	9/47 (19.1%)	7/49 (14.3%)	8/50 (16.0%)	5/46 (10.9%)
	Poly-K Incidence	7/33.7 (20.8%)	10/34.8 (28.7%)	9/32.4 (27.7%)	7/35.0 (20.0%)	8/37.9 (21.1%)	5/32.8 (15.3%)
	Terminal Incidence	2/11 (18.2%)	2/12 (16.7%)	4/13 (30.8%)	3/13 (23.1%)	3/17 (17.6%)	1/13 (7.7%)
	Time-to-First	502	411	505	541	390	462
	Poly-K P-Value	0.176N	0.310	0.350	0.588N	0.600	0.395N
Kidney * Cyst, Renal Tubule	Simple Incidence	7/49 (14.3%)	15/50 (30.0%)	11/47 (23.4%)	8/49 (16.3%)	16/50 (32.0%)	11/46 (23.9%)
	Poly-K Incidence	7/33.6 (20.8%)	15/34.9 (43.0%)	11/34.3 (32.1%)	8/36.1 (22.1%)	16/39.6 (40.4%)	11/34.4 (32.0%)
	Terminal Incidence	2/11 (18.2%)	6/12 (50.0%)	2/13 (15.4%)	3/13 (23.1%)	8/17 (47.1%)	4/13 (30.8%)
	Time-to-First	509	474	339	461	141	446
	Poly-K P-Value	0.283	0.036 *	0.212	0.564	0.054	0.216
Kidney * Hyperplasia, Transitional Epithelium	Simple Incidence	5/49 (10.2%)	6/50 (12.0%)	2/47 (4.3%)	5/49 (10.2%)	4/50 (8.0%)	8/46 (17.4%)
	Poly-K Incidence	5/32.4 (15.4%)	6/32.4 (18.5%)	2/30.6 (6.5%)	5/34.1 (14.7%)	4/35.6 (11.2%)	8/32.1 (24.9%)
	Terminal Incidence	1/11 (9.1%)	3/12 (25.0%)	1/13 (7.7%)	4/13 (30.8%)	2/17 (11.8%)	3/13 (23.1%)
	Time-to-First	514	561	540	541	568	621
	Poly-K P-Value	0.287	0.499	0.233N	0.602N	0.441N	0.257
	Severity Profile	4 1 0 0	6 0 0 0	2 0 0 0	3 2 0 0	4 0 0 0	2 5 0 1
	JT/SW P-Value	0.190	0.404	0.730	0.604	0.717	0.129
	RTE P-Value	0.175	0.401	0.160N	0.487	0.351N	0.101

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 7. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Kidney * Mineralization	Simple Incidence	28/49 (57.1%)	22/50 (44.0%)	28/47 (59.6%)	26/49 (53.1%)	23/50 (46.0%)	23/46 (50.0%)
	Poly-K Incidence	28/40.7 (68.8%)	22/39.1 (56.2%)	28/38.9 (72.0%)	26/42.4 (61.3%)	23/42.4 (54.3%)	23/39.1 (58.9%)
	Terminal Incidence	8/11 (72.7%)	5/12 (41.7%)	10/13 (76.9%)	7/13 (53.8%)	5/17 (29.4%)	8/13 (61.5%)
	Time-to-First	467	446	339	448	447	393
	Poly-K P-Value	0.132N	0.156N	0.473	0.301N	0.113N	0.227N
	Severity Profile	20 7 0 1	14 7 1 0	18 9 0 1	17 8 1 0	11 9 3 0	13 9 1 0
	JT/SW P-Value	0.481N	0.146N	0.445N	0.489N	0.440N	0.485N
	RTE P-Value	0.478N	0.158N	0.344	0.414N	0.337N	0.388N
Kidney * Nephropathy	Simple Incidence	28/49 (57.1%)	25/50 (50.0%)	25/47 (53.2%)	29/49 (59.2%)	33/50 (66.0%)	30/46 (65.2%)
	Poly-K Incidence	28/39.2 (71.4%)	25/41.3 (60.5%)	25/38.4 (65.1%)	29/40.9 (71.0%)	33/43.3 (76.3%)	30/39.9 (75.1%)
	Terminal Incidence	7/11 (63.6%)	6/12 (50.0%)	6/13 (46.2%)	8/13 (61.5%)	14/17 (82.4%)	9/13 (69.2%)
	Time-to-First	259	400	442	485	447	446
	Poly-K P-Value	0.094	0.190N	0.347N	0.588N	0.390	0.449
	Severity Profile	17 8 1 2	16 4 2 3	17 3 5 0	22 5 1 1	15 11 3 4	10 11 6 3
	JT/SW P-Value	0.006 **	0.741	0.771	0.719	0.105	0.056
	RTE P-Value	0.006 **	0.276N	0.324N	0.392N	0.083	0.041 *

P-values for dose trend are presented in the “Control” column.

N indicates a negative trend or negative treatment comparison to control with corresponding lower-tail p-values.

¹ Nonsignificant SW test due to the assumption of monotonicity.

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 8. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Alimentary System							
Liver * Angiectasis	Simple Incidence	3/50 (6.0%)	4/48 (8.3%)	8/48 (16.7%)	5/50 (10.0%)	4/50 (8.0%)	3/46 (6.5%)
	Poly-K Incidence	3/37.3 (8.0%)	4/34.6 (11.5%)	8/36.1 (22.2%)	5/31.5 (15.9%)	4/36.5 (11.0%)	3/28.7 (10.5%)
	Terminal Incidence	1/17 (5.9%)	2/16 (12.5%)	2/16 (12.5%)	3/13 (23.1%)	2/15 (13.3%)	1/9 (11.1%)
	Time-to-First	666	395	638	558	631	445
	Poly-K P-Value	0.448	0.459	0.082	0.263	0.488	0.537
	Severity Profile	0 2 0 1	1 2 1 0	2 6 0 0	0 5 0 0	0 3 1 0	1 2 0 0
	JT/SW P-Value	0.444N	0.661N	0.907N	0.849N	0.771N	0.661N
	RTE P-Value	0.432N	0.357	0.047 *	0.255	0.367	0.488
Liver * Basophilic Focus	Simple Incidence	9/50 (18.0%)	4/48 (8.3%)	5/48 (10.4%)	9/50 (18.0%)	11/50 (22.0%)	5/46 (10.9%)
	Poly-K Incidence	9/38.0 (23.7%)	4/34.8 (11.5%)	5/35.6 (14.0%)	9/32.7 (27.5%)	11/38.0 (29.0%)	5/28.4 (17.6%)
	Terminal Incidence	3/17 (17.6%)	2/16 (12.5%)	2/16 (12.5%)	4/13 (30.8%)	4/15 (26.7%)	1/9 (11.1%)
	Time-to-First	621	395	539	443	482	641
	Poly-K P-Value	0.242	0.143N	0.221N	0.460	0.395	0.385N
Liver * Clear Cell Focus	Simple Incidence	7/50 (14.0%)	9/48 (18.8%)	11/48 (22.9%)	10/50 (20.0%)	10/50 (20.0%)	7/46 (15.2%)
	Poly-K Incidence	7/38.3 (18.3%)	9/34.2 (26.3%)	11/37.4 (29.4%)	10/33.2 (30.1%)	10/36.0 (27.7%)	7/28.4 (24.6%)
	Terminal Incidence	4/17 (23.5%)	7/16 (43.8%)	5/16 (31.3%)	5/13 (38.5%)	8/15 (53.3%)	5/9 (55.6%)
	Time-to-First	483	608	489	443	700	539
	Poly-K P-Value	0.241	0.291	0.188	0.181	0.240	0.372
Liver * Degeneration,Cystic	Simple Incidence	28/50 (56.0%)	24/48 (50.0%)	25/48 (52.1%)	20/50 (40.0%)	30/50 (60.0%)	18/46 (39.1%)
	Poly-K Incidence	28/42.3 (66.2%)	24/39.1 (61.4%)	25/40.6 (61.6%)	20/38.1 (52.6%)	30/41.3 (72.7%)	18/31.1 (57.8%)
	Terminal Incidence	11/17 (64.7%)	11/16 (68.8%)	9/16 (56.3%)	7/13 (53.8%)	10/15 (66.7%)	6/9 (66.7%)
	Time-to-First	448	395	477	343	482	474
	Poly-K P-Value	0.461N	0.404N	0.411N	0.135N	0.332	0.297N
	Severity Profile	13 14 1 0	15 7 0 2	11 10 2 2	14 5 0 1	12 17 1 0	5 11 2 0
	JT/SW P-Value	0.286N	0.191N	0.371N	0.032N* ¹	0.327N	0.161N
	RTE P-Value	0.275N	0.202N	0.440N	0.030N*	0.295	0.119N
Liver * Fatty Change	Simple Incidence	5/50 (10.0%)	2/48 (4.2%)	7/48 (14.6%)	6/50 (12.0%)	1/50 (2.0%)	1/46 (2.2%)
	Poly-K Incidence	5/38.9 (12.9%)	2/34.4 (5.8%)	7/36.2 (19.3%)	6/33.4 (17.9%)	1/36.2 (2.8%)	1/28.1 (3.6%)
	Terminal Incidence	0/17 (0.0%)	0/16 (0.0%)	2/16 (12.5%)	0/13 (0.0%)	0/15 (0.0%)	0/9 (0.0%)
	Time-to-First	552	529	516	343	631	507
	Poly-K P-Value	0.128N	0.265N	0.326	0.393	0.116N	0.192N
	Severity Profile	1 3 1 0	0 0 0 2	2 2 1 2	2 1 1 2	0 0 0 1	0 0 0 1
	JT/SW P-Value	0.071N	0.150N	0.562N	0.658N	0.111N	0.105N
	RTE P-Value	0.070N	0.187N	0.168	0.341	0.085N	0.096N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 8. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Liver * Fibrosis,Biliary Tract	Simple Incidence	24/50 (48.0%)	19/48 (39.6%)	20/48 (41.7%)	12/50 (24.0%)	17/50 (34.0%)	18/46 (39.1%)
	Poly-K Incidence	24/40.4 (59.5%)	19/36.5 (52.1%)	20/38.4 (52.1%)	12/35.3 (34.0%)	17/38.2 (44.5%)	18/31.4 (57.3%)
	Terminal Incidence	10/17 (58.8%)	11/16 (68.8%)	9/16 (56.3%)	2/13 (15.4%)	7/15 (46.7%)	6/9 (66.7%)
	Time-to-First	555	516	495	468	507	487
	Poly-K P-Value	0.157N	0.327N	0.324N	0.017N*	0.121N	0.525N
	Severity Profile	14 10 0 0	11 8 0 0	14 5 1 0	9 3 0 0	12 5 0 0	11 7 0 0
	JT/SW P-Value	0.065N	0.214N	0.255N	0.005N** ¹	0.021N* ¹	0.056N
	RTE P-Value	0.068N	0.197N	0.212N	0.005N**	0.050N*	0.169N
Liver * Hepatodiaphragmatic Nodule	Simple Incidence	3/50 (6.0%)	3/48 (6.3%)	1/48 (2.1%)	5/50 (10.0%)	4/50 (8.0%)	5/46 (10.9%)
	Poly-K Incidence	3/37.6 (8.0%)	3/34.3 (8.7%)	1/35.2 (2.8%)	5/33.1 (15.1%)	4/37.7 (10.6%)	5/28.8 (17.4%)
	Terminal Incidence	2/17 (11.8%)	1/16 (6.3%)	0/16 (0.0%)	1/13 (7.7%)	0/15 (0.0%)	2/9 (22.2%)
	Time-to-First	448	575	607	399	517	558
	Poly-K P-Value	0.102	0.621	0.328N	0.284	0.501	0.217
Liver * Hyperplasia,Bile Duct	Simple Incidence	19/50 (38.0%)	20/48 (41.7%)	19/48 (39.6%)	12/50 (24.0%)	20/50 (40.0%)	13/46 (28.3%)
	Poly-K Incidence	19/39.5 (48.1%)	20/38.8 (51.6%)	19/38.9 (48.8%)	12/34.0 (35.3%)	20/40.3 (49.6%)	13/30.0 (43.3%)
	Terminal Incidence	10/17 (58.8%)	9/16 (56.3%)	9/16 (56.3%)	6/13 (46.2%)	7/15 (46.7%)	5/9 (55.6%)
	Time-to-First	554	435	495	443	465	492
	Poly-K P-Value	0.298N	0.465	0.565	0.182N	0.535	0.438N
	Severity Profile	11 6 2 0	7 9 3 1	6 10 3 0	6 5 1 0	10 5 5 0	1 8 2 2
	JT/SW P-Value	0.233N	0.770N	0.787N	0.123N	0.434N	0.460N
	RTE P-Value	0.226N	0.238	0.311	0.099N	0.344	0.362N
Liver * Hyperplasia,Oval Cell	Simple Incidence	3/50 (6.0%)	1/48 (2.1%)	5/48 (10.4%)	0/50 (0.0%)	1/50 (2.0%)	3/46 (6.5%)
	Poly-K Incidence	3/37.2 (8.1%)	1/33.7 (3.0%)	5/35.6 (14.0%)	0/30.8 (0.0%)	1/35.8 (2.8%)	3/28.3 (10.6%)
	Terminal Incidence	2/17 (11.8%)	0/16 (0.0%)	2/16 (12.5%)	0/13 (0.0%)	1/15 (6.7%)	0/9 (0.0%)
	Time-to-First	616	660	552	----	727 (T)	492
	Poly-K P-Value	0.435N	0.340N	0.329	0.155N	0.317N	0.531
	Severity Profile	1 2 0 0	0 0 0 1	3 2 0 0	---	1 0 0 0	1 2 0 0
	JT/SW P-Value	0.348N	0.173N	0.603N	0.095N	0.132N	0.295N
	RTE P-Value	0.368N	0.196N	0.126	0.070N	0.131N	0.450
Liver * Infiltration Cellular,Mononuclear Cell	Simple Incidence	34/50 (68.0%)	40/48 (83.3%)	37/48 (77.1%)	33/50 (66.0%)	33/50 (66.0%)	29/46 (63.0%)
	Poly-K Incidence	34/43.3 (78.6%)	40/44.0 (90.9%)	37/43.7 (84.8%)	33/41.6 (79.4%)	33/42.3 (78.1%)	29/37.0 (78.4%)
	Terminal Incidence	15/17 (88.2%)	16/16 (100.0%)	14/16 (87.5%)	11/13 (84.6%)	12/15 (80.0%)	7/9 (77.8%)
	Time-to-First	483	349	477	403	482	445
	Poly-K P-Value	0.164N	0.064	0.300	0.580	0.591N	0.611N
	Severity Profile	19 15 0 0	27 13 0 0	19 18 0 0	26 7 0 0	23 10 0 0	15 13 1 0
	JT/SW P-Value	0.073N	0.790N	0.892N	0.138N	0.206N	0.312N
	RTE P-Value	0.073N	0.198	0.132	0.119N	0.215N	0.400N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 8. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Liver * Vacuolization Cytoplasmic	Simple Incidence	14/50 (28.0%)	9/48 (18.8%)	17/48 (35.4%)	12/50 (24.0%)	12/50 (24.0%)	13/46 (28.3%)
	Poly-K Incidence	14/38.7 (36.2%)	9/34.1 (26.4%)	17/39.2 (43.4%)	12/33.7 (35.6%)	12/39.0 (30.7%)	13/33.3 (39.1%)
	Terminal Incidence	9/17 (52.9%)	7/16 (43.8%)	7/16 (43.8%)	6/13 (46.2%)	5/15 (33.3%)	3/9 (33.3%)
	Time-to-First	483	558	404	474	482	121
	Poly-K P-Value	0.449	0.254N	0.332	0.579N	0.393N	0.495
	Severity Profile	4 9 1 0	3 4 2 0	5 12 0 0	6 5 1 0	6 6 0 0	9 4 0 0
	JT/SW P-Value	0.373N	0.152N	0.534N	0.355N	0.349N	0.408N
	RTE P-Value	0.383N	0.155N	0.212	0.273N	0.262N	0.375N
Pancreas * Basophilic Focus	Simple Incidence	1/47 (2.1%)	1/46 (2.2%)	4/47 (8.5%)	2/49 (4.1%)	0/50 (0.0%)	1/44 (2.3%)
	Poly-K Incidence	1/35.5 (2.8%)	1/32.1 (3.1%)	4/34.0 (11.8%)	2/31.4 (6.4%)	0/35.8 (0.0%)	1/27.5 (3.6%)
	Terminal Incidence	1/17 (5.9%)	1/16 (6.3%)	4/16 (25.0%)	0/13 (0.0%)	0/15 (0.0%)	0/9 (0.0%)
	Time-to-First	726 (T)	725 (T)	724 (T)	443	---	600
	Poly-K P-Value	0.409N	0.739	0.162	0.457	0.498N	0.702
Pancreas * Degeneration,Acinus	Simple Incidence	41/47 (87.2%)	38/46 (82.6%)	34/47 (72.3%)	41/49 (83.7%)	41/50 (82.0%)	34/44 (77.3%)
	Poly-K Incidence	41/45.1 (90.9%)	38/43.0 (88.5%)	34/43.6 (77.9%)	41/46.6 (88.1%)	41/45.6 (89.9%)	34/39.0 (87.3%)
	Terminal Incidence	17/17 (100.0%)	14/16 (87.5%)	13/16 (81.3%)	11/13 (84.6%)	14/15 (93.3%)	9/9 (100.0%)
	Time-to-First	392	349	393	343	432	358
	Poly-K P-Value	0.472N	0.486N	0.059N	0.451N	0.581N	0.414N
	Severity Profile	8 10 15 8	8 10 13 7	4 15 9 6	9 18 9 5	9 18 9 5	9 11 9 5
	JT/SW P-Value	0.028N*	0.273N	0.072N	0.081N	0.071N	0.053N
	RTE P-Value	0.031N*	0.264N	0.053N	0.078N	0.058N	0.044N*
Pancreas * Infiltration Cellular,Lymphocyte	Simple Incidence	37/47 (78.7%)	35/46 (76.1%)	32/47 (68.1%)	37/49 (75.5%)	40/50 (80.0%)	32/44 (72.7%)
	Poly-K Incidence	37/44.1 (83.9%)	35/41.4 (84.6%)	32/41.6 (77.0%)	37/44.1 (83.8%)	40/45.8 (87.3%)	32/39.4 (81.3%)
	Terminal Incidence	15/17 (88.2%)	13/16 (81.3%)	13/16 (81.3%)	11/13 (84.6%)	13/15 (86.7%)	7/9 (77.8%)
	Time-to-First	392	349	477	343	432	358
	Poly-K P-Value	0.495	0.594	0.276N	0.619N	0.432	0.485N
	Severity Profile	11 20 6 0	11 19 5 0	13 12 7 0	14 23 0 0	16 21 2 1	15 12 5 0
	JT/SW P-Value	0.122N	0.353N	0.142N	0.141N	0.195N	0.132N
	RTE P-Value	0.119N	0.352N	0.103N	0.120N	0.263N	0.104N
Pancreas * Lipomatosis	Simple Incidence	13/47 (27.7%)	9/46 (19.6%)	15/47 (31.9%)	9/49 (18.4%)	10/50 (20.0%)	13/44 (29.5%)
	Poly-K Incidence	13/38.0 (34.2%)	9/33.4 (27.0%)	15/36.2 (41.5%)	9/33.3 (27.0%)	10/37.4 (26.8%)	13/30.8 (42.2%)
	Terminal Incidence	6/17 (35.3%)	5/16 (31.3%)	6/16 (37.5%)	3/13 (23.1%)	3/15 (20.0%)	3/9 (33.3%)
	Time-to-First	552	558	477	506	602	474
	Poly-K P-Value	0.438	0.339N	0.339	0.342N	0.321N	0.330
	Severity Profile	0 5 5 3	0 2 5 2	0 4 9 2	0 5 3 1	0 2 4 4	0 4 6 3
	JT/SW P-Value	0.474N	0.203N	0.518N	0.156N	0.228N	0.395N
	RTE P-Value	0.498	0.206N	0.312	0.133N	0.238N	0.401

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 8. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Pancreas * Pigmentation	Simple Incidence	23/47 (48.9%)	33/46 (71.7%)	20/47 (42.6%)	28/49 (57.1%)	23/50 (46.0%)	21/44 (47.7%)
	Poly-K Incidence	23/41.4 (55.5%)	33/42.3 (78.0%)	20/40.6 (49.3%)	28/43.1 (65.0%)	23/41.6 (55.3%)	21/34.7 (60.5%)
	Terminal Incidence	8/17 (47.1%)	12/16 (75.0%)	8/16 (50.0%)	6/13 (46.2%)	9/15 (60.0%)	3/9 (33.3%)
	Time-to-First	392	349	393	343	432	358
	Poly-K P-Value	0.312N	0.018 *	0.360N	0.241	0.581N	0.417
	Severity Profile	20 3 0 0	23 10 0 0	15 5 0 0	24 3 1 0	16 7 0 0	12 9 0 0
	JT/SW P-Value	0.289N	0.996N	0.453N	0.722N	0.694N	0.765N
	RTE P-Value	0.288N	0.005 **	0.379N	0.218	0.447	0.284
Pancreas * Polyarteritis	Simple Incidence	0/47 (0.0%)	1/46 (2.2%)	1/47 (2.1%)	2/49 (4.1%)	5/50 (10.0%)	2/44 (4.5%)
	Poly-K Incidence	0/35.5 (0.0%)	1/32.1 (3.1%)	1/34.6 (2.9%)	2/31.6 (6.3%)	5/37.9 (13.2%)	2/28.3 (7.1%)
	Terminal Incidence	0/17 (0.0%)	1/16 (6.3%)	0/16 (0.0%)	0/13 (0.0%)	1/15 (6.7%)	0/9 (0.0%)
	Time-to-First	----	726 (T)	512	497	432	474
	Poly-K P-Value	0.013 *	0.480	0.495	0.211	0.035 *	0.189
	Severity Profile	---	0 0 0 1	1 0 0 0	1 0 0 1	1 2 1 1	1 0 0 1
	JT/SW P-Value	0.018 *	0.156	0.228	0.104	0.006 **	0.042 *
	RTE P-Value	0.025 *	0.289	0.301	0.121	0.007 **	0.153
Cardiovascular System							
Blood Vessel * Mineralization	Simple Incidence	8/50 (16.0%)	2/48 (4.2%)	6/48 (12.5%)	4/50 (8.0%)	7/50 (14.0%)	4/46 (8.7%)
	Poly-K Incidence	8/39.0 (20.5%)	2/34.1 (5.9%)	6/37.3 (16.1%)	4/32.1 (12.5%)	7/38.3 (18.3%)	4/28.0 (14.3%)
	Terminal Incidence	1/17 (5.9%)	1/16 (6.3%)	0/16 (0.0%)	2/13 (15.4%)	0/15 (0.0%)	1/9 (11.1%)
	Time-to-First	574	481	477	498	517	593
	Poly-K P-Value	0.521N	0.067N	0.419N	0.280N	0.517N	0.371N
	Severity Profile	0 0 1 7	0 0 0 2	0 1 2 3	1 1 0 2	0 1 1 5	1 0 0 3
	JT/SW P-Value	0.356N	0.028N* ¹	0.122N	0.100N	0.187N	0.151N
	RTE P-Value	0.359N	0.027N*	0.259N	0.074N	0.356N	0.108N
Heart * Cardiomyopathy	Simple Incidence	45/50 (90.0%)	44/48 (91.7%)	45/48 (93.8%)	48/50 (96.0%)	47/50 (94.0%)	41/46 (89.1%)
	Poly-K Incidence	45/48.1 (93.5%)	44/45.7 (96.3%)	45/46.0 (97.9%)	48/48.9 (98.2%)	47/47.4 (99.1%)	41/41.7 (98.2%)
	Terminal Incidence	16/17 (94.1%)	16/16 (100.0%)	16/16 (100.0%)	13/13 (100.0%)	15/15 (100.0%)	9/9 (100.0%)
	Time-to-First	47	349	404	343	432	445
	Poly-K P-Value	0.022 *	0.433	0.261	0.217	0.142	0.243
	Severity Profile	8 20 11 6	13 18 7 6	10 16 12 7	15 21 10 2	12 13 12 10	9 16 10 6
	JT/SW P-Value	0.371	0.787	0.408	0.750	0.342	0.535
	RTE P-Value	0.372	0.219N	0.343	0.153N	0.258	0.428N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 8. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Heart * Mineralization	Simple Incidence	9/50 (18.0%)	1/48 (2.1%)	6/48 (12.5%)	2/50 (4.0%)	7/50 (14.0%)	4/46 (8.7%)
	Poly-K Incidence	9/39.6 (22.7%)	1/34.1 (2.9%)	6/37.3 (16.1%)	2/32.1 (6.2%)	7/38.3 (18.3%)	4/28.7 (13.9%)
	Terminal Incidence	1/17 (5.9%)	0/16 (0.0%)	0/16 (0.0%)	0/13 (0.0%)	0/15 (0.0%)	0/9 (0.0%)
	Time-to-First	555	481	477	498	517	480
	Poly-K P-Value	0.398N	0.014N*	0.325N	0.053N	0.419N	0.274N
	Severity Profile	0 1 3 5	0 0 0 1	0 1 3 2	0 1 0 1	0 1 1 5	0 1 1 2
	JT/SW P-Value	0.287N	0.005N** ¹	0.050N	0.008N** ¹	0.065N	0.071N
	RTE P-Value	0.294N	0.006N**	0.164N	0.009N**	0.259N	0.064N
Endocrine System							
Adrenal Cortex * Hyperplasia	Simple Incidence	5/47 (10.6%)	7/47 (14.9%)	6/48 (12.5%)	4/49 (8.2%)	5/50 (10.0%)	4/44 (9.1%)
	Poly-K Incidence	5/35.5 (14.1%)	7/34.1 (20.5%)	6/35.4 (16.9%)	4/31.4 (12.7%)	5/36.1 (13.9%)	4/28.1 (14.2%)
	Terminal Incidence	4/17 (23.5%)	3/16 (18.8%)	4/16 (25.0%)	2/13 (15.4%)	4/15 (26.7%)	0/9 (0.0%)
	Time-to-First	714	575	587	573	664	539
	Poly-K P-Value	0.359N	0.345	0.498	0.579N	0.624N	0.633
	Severity Profile	4 1 0 0	1 5 1 0	0 4 2 0	2 2 0 0	2 3 0 0	3 0 1 0
	JT/SW P-Value	0.238N	0.779N	0.764N	0.474N	0.556N	0.559N
	RTE P-Value	0.238N	0.215	0.321	0.370N	0.486N	0.423N
Adrenal Cortex * Hypertrophy	Simple Incidence	2/47 (4.3%)	2/47 (4.3%)	0/48 (0.0%)	4/49 (8.2%)	3/50 (6.0%)	2/44 (4.5%)
	Poly-K Incidence	2/36.0 (5.5%)	2/33.3 (6.0%)	0/34.8 (0.0%)	4/32.0 (12.5%)	3/36.3 (8.3%)	2/27.6 (7.2%)
	Terminal Incidence	1/17 (5.9%)	1/16 (6.3%)	0/16 (0.0%)	1/13 (7.7%)	1/15 (6.7%)	0/9 (0.0%)
	Time-to-First	552	516	----	474	624	600
	Poly-K P-Value	0.245	0.667	0.244N	0.281	0.503	0.595
	Severity Profile	1 0 0 1	2 0 0 0	---	1 2 1 0	1 2 0 0	1 1 0 0
	JT/SW P-Value	0.270	0.509	0.822	0.216	0.336	0.434
	RTE P-Value	0.281	0.487N	0.164N	0.202	0.344	0.479
Adrenal Cortex * Vacuolization Cytoplasmic	Simple Incidence	21/47 (44.7%)	20/47 (42.6%)	19/48 (39.6%)	18/49 (36.7%)	18/50 (36.0%)	20/44 (45.5%)
	Poly-K Incidence	21/40.4 (52.0%)	20/36.3 (55.2%)	19/39.2 (48.5%)	18/36.3 (49.6%)	18/39.4 (45.7%)	20/33.5 (59.7%)
	Terminal Incidence	9/17 (52.9%)	12/16 (75.0%)	9/16 (56.3%)	7/13 (53.8%)	7/15 (46.7%)	5/9 (55.6%)
	Time-to-First	448	481	489	403	507	445
	Poly-K P-Value	0.486	0.479	0.465N	0.509N	0.364N	0.325
	Severity Profile	5 12 4 0	2 14 4 0	7 11 0 1	3 11 4 0	7 10 1 0	3 14 3 0
	JT/SW P-Value	0.314N	0.505N	0.248N	0.300N	0.157N	0.359N
	RTE P-Value	0.335N	0.499	0.209N	0.259N	0.119N	0.441

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 8. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Adrenal Medulla * Hyperplasia	Simple Incidence	8/47 (17.0%)	9/46 (19.6%)	10/48 (20.8%)	7/49 (14.3%)	17/50 (34.0%)	11/44 (25.0%)
	Poly-K Incidence	8/36.5 (21.9%)	9/33.9 (26.6%)	10/37.5 (26.7%)	7/31.0 (22.6%)	17/38.6 (44.1%)	11/28.4 (38.8%)
	Terminal Incidence	4/17 (23.5%)	3/16 (18.8%)	3/16 (18.8%)	5/13 (38.5%)	8/15 (53.3%)	3/9 (33.3%)
	Time-to-First	605	589	534	632	517	539
	Poly-K P-Value	0.016 *	0.427	0.416	0.591	0.030 *	0.108
	Severity Profile	2 5 1 0	4 3 1 1	6 1 2 1	2 4 1 0	8 5 1 3	3 7 0 1
	JT/SW P-Value	0.059	0.390	0.412	0.569	0.029 * ¹	0.099
	RTE P-Value	0.066	0.399	0.360	0.369N	0.025 *	0.182
Parathyroid Gland * Hyperplasia	Simple Incidence	22/49 (44.9%)	17/46 (37.0%)	27/46 (58.7%)	23/49 (46.9%)	30/50 (60.0%)	23/43 (53.5%)
	Poly-K Incidence	22/41.9 (52.5%)	17/36.6 (46.4%)	27/39.4 (68.6%)	23/38.0 (60.5%)	30/44.1 (68.0%)	23/34.1 (67.4%)
	Terminal Incidence	6/16 (37.5%)	8/16 (50.0%)	9/16 (56.3%)	7/13 (53.8%)	7/15 (46.7%)	5/9 (55.6%)
	Time-to-First	392	395	477	403	432	445
	Poly-K P-Value	0.018 *	0.374N	0.092	0.301	0.095	0.127
	Severity Profile	1 8 7 6	2 10 0 5	4 15 5 3	8 8 5 2	3 12 6 9	7 7 5 4
	JT/SW P-Value	0.122	0.863	0.344	0.643	0.120	0.314
	RTE P-Value	0.131	0.119N	0.285	0.232N	0.090	0.464
Pituitary Gland * Angiectasis	Simple Incidence	14/46 (30.4%)	6/48 (12.5%)	7/48 (14.6%)	9/49 (18.4%)	10/50 (20.0%)	6/43 (14.0%)
	Poly-K Incidence	14/37.1 (37.7%)	6/34.8 (17.2%)	7/35.5 (19.7%)	9/32.1 (28.1%)	10/37.4 (26.8%)	6/29.3 (20.5%)
	Terminal Incidence	7/17 (41.2%)	2/16 (12.5%)	3/16 (18.8%)	6/13 (46.2%)	4/15 (26.7%)	1/9 (11.1%)
	Time-to-First	554	555	667	558	555	465
	Poly-K P-Value	0.194N	0.042N*	0.070N	0.272N	0.217N	0.101N
	Severity Profile	0 2 3 9	0 1 0 5	0 0 0 7	0 0 1 8	0 0 1 9	0 0 1 5
	JT/SW P-Value	0.163N	0.021N* ¹	0.030N* ¹	0.050N* ¹	0.073N	0.039N*
	RTE P-Value	0.147N	0.020N*	0.036N*	0.089N	0.131N	0.029N*
Pituitary Gland * Cyst,Pars Distalis	Simple Incidence	4/46 (8.7%)	6/48 (12.5%)	5/48 (10.4%)	10/49 (20.4%)	11/50 (22.0%)	5/43 (11.6%)
	Poly-K Incidence	4/35.8 (11.2%)	6/34.7 (17.3%)	5/35.1 (14.3%)	10/33.6 (29.7%)	11/38.6 (28.5%)	5/29.1 (17.2%)
	Terminal Incidence	1/17 (5.9%)	4/16 (25.0%)	4/16 (25.0%)	2/13 (15.4%)	6/15 (40.0%)	1/9 (11.1%)
	Time-to-First	555	449	648	468	426	537
	Poly-K P-Value	0.056	0.346	0.487	0.047 *	0.053	0.369
Pituitary Gland * Hyperplasia,Pars Distalis	Simple Incidence	12/46 (26.1%)	16/48 (33.3%)	18/48 (37.5%)	15/49 (30.6%)	19/50 (38.0%)	19/43 (44.2%)
	Poly-K Incidence	12/37.2 (32.3%)	16/38.2 (41.9%)	18/40.8 (44.1%)	15/37.3 (40.2%)	19/38.9 (48.9%)	19/32.7 (58.1%)
	Terminal Incidence	5/17 (29.4%)	6/16 (37.5%)	5/16 (31.3%)	2/13 (15.4%)	9/15 (60.0%)	6/9 (66.7%)
	Time-to-First	392	395	393	468	482	480
	Poly-K P-Value	0.018 *	0.259	0.194	0.312	0.097	0.020 *
	Severity Profile	0 6 3 3	5 4 6 1	4 8 2 4	3 6 3 3	3 9 5 2	4 8 3 4
	JT/SW P-Value	0.073	0.315	0.213	0.346	0.214	0.081
	RTE P-Value	0.074	0.337	0.192	0.395	0.183	0.064

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 8. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Pituitary Gland * Hypertrophy,Pars Distalis	Simple Incidence	1/46 (2.2%)	2/48 (4.2%)	3/48 (6.3%)	3/49 (6.1%)	1/50 (2.0%)	4/43 (9.3%)
	Poly-K Incidence	1/35.1 (2.8%)	2/33.7 (5.9%)	3/35.3 (8.5%)	3/31.6 (9.5%)	1/35.8 (2.8%)	4/28.5 (14.1%)
	Terminal Incidence	0/17 (0.0%)	1/16 (6.3%)	1/16 (6.3%)	1/13 (7.7%)	1/15 (6.7%)	0/9 (0.0%)
	Time-to-First	675	660	582	540	727 (T)	537
	Poly-K P-Value	0.149	0.486	0.306	0.266	0.757N	0.118
	Severity Profile	0 0 1 0	0 1 1 0	1 2 0 0	0 3 0 0	0 1 0 0	0 4 0 0
	JT/SW P-Value	0.166	0.297	0.208	0.240	0.360	0.083
	RTE P-Value	0.150	0.330	0.242	0.217	0.476N	0.084
Thyroid Gland * Hyperplasia,C-Cell	Simple Incidence	12/43 (27.9%)	18/45 (40.0%)	11/44 (25.0%)	19/45 (42.2%)	18/48 (37.5%)	13/42 (31.0%)
	Poly-K Incidence	12/36.4 (33.0%)	18/35.2 (51.1%)	11/33.8 (32.6%)	19/35.2 (53.9%)	18/39.3 (45.8%)	13/31.0 (41.9%)
	Terminal Incidence	4/17 (23.5%)	8/16 (50.0%)	5/16 (31.3%)	6/13 (46.2%)	9/15 (60.0%)	3/9 (33.3%)
	Time-to-First	483	395	539	343	432	445
	Poly-K P-Value	0.210	0.085	0.588N	0.052	0.176	0.304
	Severity Profile	4 7 1 0	10 6 2 0	4 5 1 1	11 6 2 0	10 7 1 0	5 6 1 1
	JT/SW P-Value	0.359	0.168	0.421	0.159	0.233	0.322
	RTE P-Value	0.361	0.170	0.396N	0.128	0.239	0.383
Thyroid Gland * Hyperplasia,Follicular Cell	Simple Incidence	6/43 (14.0%)	6/45 (13.3%)	9/44 (20.5%)	10/45 (22.2%)	6/48 (12.5%)	7/42 (16.7%)
	Poly-K Incidence	6/34.7 (17.3%)	6/34.0 (17.7%)	9/35.5 (25.4%)	10/32.3 (31.0%)	6/36.6 (16.4%)	7/28.9 (24.3%)
	Terminal Incidence	1/17 (5.9%)	0/16 (0.0%)	1/16 (6.3%)	0/13 (0.0%)	1/15 (6.7%)	1/9 (11.1%)
	Time-to-First	392	529	477	403	602	474
	Poly-K P-Value	0.303	0.609	0.295	0.148	0.586N	0.354
	Severity Profile	0 3 3 0	0 2 4 0	0 2 6 1	0 3 7 0	0 3 3 0	0 3 4 0
	JT/SW P-Value	0.416	0.517	0.208	0.181	0.358	0.400
	RTE P-Value	0.401	0.488N	0.169	0.138	0.429N	0.364
Thyroid Gland * Ultimobranchial Cyst	Simple Incidence	3/43 (7.0%)	5/45 (11.1%)	5/44 (11.4%)	2/45 (4.4%)	5/48 (10.4%)	4/42 (9.5%)
	Poly-K Incidence	3/33.5 (9.0%)	5/32.8 (15.2%)	5/33.1 (15.1%)	2/29.2 (6.8%)	5/36.2 (13.8%)	4/28.0 (14.3%)
	Terminal Incidence	2/17 (11.8%)	2/16 (12.5%)	3/16 (18.8%)	0/13 (0.0%)	2/15 (13.3%)	0/9 (0.0%)
	Time-to-First	518	529	404	403	652	253
	Poly-K P-Value	0.401	0.341	0.346	0.562N	0.397	0.401
Genital System							
Coagulating Gland * Atrophy	Simple Incidence	1/45 (2.2%)	1/45 (2.2%)	4/44 (9.1%)	1/50 (2.0%)	2/48 (4.2%)	2/44 (4.5%)
	Poly-K Incidence	1/34.8 (2.9%)	1/31.6 (3.2%)	4/33.2 (12.0%)	1/31.4 (3.2%)	2/36.1 (5.5%)	2/27.3 (7.3%)
	Terminal Incidence	0/17 (0.0%)	0/16 (0.0%)	1/16 (6.3%)	0/13 (0.0%)	0/15 (0.0%)	0/9 (0.0%)
	Time-to-First	643	671	516	517	631	700
	Poly-K P-Value	0.311	0.740	0.161	0.738	0.513	0.416
	Severity Profile	0 0 1 0	0 0 1 0	0 1 1 2	0 1 0 0	0 0 2 0	0 0 1 1
	JT/SW P-Value	0.341	0.500	0.068	0.276	0.331	0.357
RTE P-Value	0.333	0.500	0.040 *	0.472N	0.317	0.283	

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 8. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Epididymis * Exfoliated Germ Cell	Simple Incidence	12/49 (24.5%)	15/48 (31.3%)	11/48 (22.9%)	13/50 (26.0%)	17/50 (34.0%)	9/46 (19.6%)
	Poly-K Incidence	12/39.0 (30.8%)	15/38.3 (39.1%)	11/37.9 (29.1%)	13/36.1 (36.0%)	17/39.8 (42.7%)	9/29.5 (30.5%)
	Terminal Incidence	3/17 (17.6%)	3/16 (18.8%)	3/16 (18.8%)	3/13 (23.1%)	3/15 (20.0%)	2/9 (22.2%)
	Time-to-First	552	395	477	343	517	558
	Poly-K P-Value	0.341	0.293	0.535N	0.405	0.187	0.596N
	Severity Profile	3 6 3 0	5 7 3 0	3 7 1 0	3 9 1 0	5 5 6 1	4 4 1 0
	JT/SW P-Value	0.415N	0.741N	0.468N	0.579N	0.770N	0.334N
	RTE P-Value	0.391N	0.254	0.397N	0.464	0.127	0.247N
Epididymis * Hypospermia	Simple Incidence	14/49 (28.6%)	10/48 (20.8%)	15/48 (31.3%)	7/50 (14.0%)	16/50 (32.0%)	8/46 (17.4%)
	Poly-K Incidence	14/40.1 (34.9%)	10/35.6 (28.1%)	15/37.6 (39.9%)	7/33.6 (20.8%)	16/39.3 (40.7%)	8/30.0 (26.6%)
	Terminal Incidence	4/17 (23.5%)	4/16 (25.0%)	7/16 (43.8%)	2/13 (15.4%)	4/15 (26.7%)	3/9 (33.3%)
	Time-to-First	483	516	404	343	555	294
	Poly-K P-Value	0.444N	0.346N	0.413	0.136N	0.380	0.314N
	Severity Profile	0 0 0 14	0 0 2 8	0 0 2 13	0 0 0 7	0 1 4 11	0 0 0 8
	JT/SW P-Value	0.205N	0.156N	0.405N	0.051N	0.280N	0.127N
	RTE P-Value	0.196N	0.158N	0.419	0.043N*	0.449	0.097N
Epididymis * Infiltration Cellular,Lymphocyte	Simple Incidence	14/49 (28.6%)	16/48 (33.3%)	16/48 (33.3%)	14/50 (28.0%)	12/50 (24.0%)	13/46 (28.3%)
	Poly-K Incidence	14/40.2 (34.8%)	16/36.8 (43.5%)	16/38.3 (41.7%)	14/35.3 (39.6%)	12/39.9 (30.1%)	13/29.6 (44.0%)
	Terminal Incidence	6/17 (35.3%)	9/16 (56.3%)	7/16 (43.8%)	6/13 (46.2%)	2/15 (13.3%)	7/9 (77.8%)
	Time-to-First	448	395	512	403	482	474
	Poly-K P-Value	0.482N	0.286	0.341	0.420	0.415N	0.294
	Severity Profile	9 5 0 0	13 3 0 0	14 2 0 0	11 3 0 0	10 2 0 0	12 1 0 0
	JT/SW P-Value	0.199N	0.629N	0.691N	0.531N	0.337N	0.429N
	RTE P-Value	0.205N	0.361	0.386	0.425N	0.255N	0.391N
Epididymis * Polyarteritis	Simple Incidence	2/49 (4.1%)	1/48 (2.1%)	3/48 (6.3%)	4/50 (8.0%)	5/50 (10.0%)	2/46 (4.3%)
	Poly-K Incidence	2/36.9 (5.4%)	1/33.4 (3.0%)	3/35.5 (8.5%)	4/33.3 (12.0%)	5/37.7 (13.2%)	2/28.0 (7.2%)
	Terminal Incidence	1/17 (5.9%)	1/16 (6.3%)	0/16 (0.0%)	0/13 (0.0%)	2/15 (13.3%)	1/9 (11.1%)
	Time-to-First	552	727 (T)	638	403	482	558
	Poly-K P-Value	0.120	0.535N	0.482	0.288	0.222	0.591
	Severity Profile	2 0 0 0	1 0 0 0	1 2 0 0	2 1 1 0	4 1 0 0	2 0 0 0
	JT/SW P-Value	0.165	0.714	0.340	0.231	0.144	0.316
	RTE P-Value	0.173	0.341N	0.311	0.156	0.118	0.478
Prostate, Dorsal/Lateral Lobe * Cyst,Mucinous	Simple Incidence	6/46 (13.0%)	2/48 (4.2%)	6/48 (12.5%)	5/50 (10.0%)	7/49 (14.3%)	4/45 (8.9%)
	Poly-K Incidence	6/36.4 (16.5%)	2/33.4 (6.0%)	6/36.2 (16.6%)	5/32.0 (15.6%)	7/37.1 (18.9%)	4/28.9 (13.8%)
	Terminal Incidence	3/17 (17.6%)	2/16 (12.5%)	3/16 (18.8%)	2/13 (15.4%)	1/15 (6.7%)	1/9 (11.1%)
	Time-to-First	578	726 (T)	495	604	593	530
	Poly-K P-Value	0.339	0.157N	0.621	0.593N	0.514	0.520N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 8. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Prostate, Dorsal/Lateral Lobe * Fibrosis	Simple Incidence	15/46 (32.6%)	8/48 (16.7%)	11/48 (22.9%)	8/50 (16.0%)	12/49 (24.5%)	6/45 (13.3%)
	Poly-K Incidence	15/38.1 (39.4%)	8/36.1 (22.2%)	11/36.7 (30.0%)	8/33.2 (24.1%)	12/38.9 (30.9%)	6/28.9 (20.8%)
	Terminal Incidence	5/17 (29.4%)	1/16 (6.3%)	5/16 (31.3%)	2/13 (15.4%)	2/15 (13.3%)	1/9 (11.1%)
	Time-to-First	578	516	552	506	551	507
	Poly-K P-Value	0.141N	0.082N	0.267N	0.124N	0.290N	0.083N
	Severity Profile	1 5 6 3	1 3 1 3	3 4 1 3	1 4 0 3	2 6 4 0	0 4 0 2
	JT/SW P-Value	0.049N*	0.039N* ¹	0.075N	0.027N* ¹	0.070N	0.012N*
	RTE P-Value	0.044N*	0.028N*	0.091N	0.018N*	0.113N	0.012N*
Prostate, Dorsal/Lateral Lobe * Infiltration Cellular,Lymphocyte	Simple Incidence	31/46 (67.4%)	30/48 (62.5%)	28/48 (58.3%)	27/50 (54.0%)	35/49 (71.4%)	22/45 (48.9%)
	Poly-K Incidence	31/41.6 (74.6%)	30/41.1 (72.9%)	28/40.0 (70.0%)	27/38.9 (69.3%)	35/42.4 (82.6%)	22/33.2 (66.3%)
	Terminal Incidence	13/17 (76.5%)	12/16 (75.0%)	12/16 (75.0%)	11/13 (84.6%)	13/15 (86.7%)	7/9 (77.8%)
	Time-to-First	552	435	477	343	432	445
	Poly-K P-Value	0.512N	0.535N	0.407N	0.382N	0.241	0.285N
	Severity Profile	17 11 1 2	20 6 1 3	15 9 2 2	16 8 1 2	20 14 1 0	14 7 0 1
	JT/SW P-Value	0.114N	0.222N	0.278N	0.119N	0.336N	0.034N*
	RTE P-Value	0.105N	0.226N	0.230N	0.096N	0.431	0.029N*
Prostate, Dorsal/Lateral Lobe * Inflammation,Suppurative	Simple Incidence	39/46 (84.8%)	46/48 (95.8%)	41/48 (85.4%)	42/50 (84.0%)	44/49 (89.8%)	38/45 (84.4%)
	Poly-K Incidence	39/43.3 (90.1%)	46/46.7 (98.4%)	41/45.4 (90.4%)	42/45.2 (93.0%)	44/46.3 (95.1%)	38/41.2 (92.3%)
	Terminal Incidence	17/17 (100.0%)	16/16 (100.0%)	14/16 (87.5%)	13/13 (100.0%)	14/15 (93.3%)	8/9 (88.9%)
	Time-to-First	392	349	393	343	432	294
	Poly-K P-Value	0.501	0.062	0.643	0.449	0.282	0.517
	Severity Profile	7 22 7 3	14 21 8 3	14 20 5 2	10 20 9 3	12 21 11 0	6 25 6 1
	JT/SW P-Value	0.371N	0.578N	0.136N	0.307N	0.393N	0.425N
	RTE P-Value	0.375N	0.411	0.118N	0.404N	0.429N	0.373N
Prostate, Ventral Lobe * Atrophy	Simple Incidence	2/48 (4.2%)	3/47 (6.4%)	4/47 (8.5%)	1/50 (2.0%)	4/49 (8.2%)	4/45 (8.9%)
	Poly-K Incidence	2/36.0 (5.6%)	3/34.0 (8.8%)	4/34.9 (11.5%)	1/31.4 (3.2%)	4/37.6 (10.6%)	4/29.0 (13.8%)
	Terminal Incidence	1/17 (5.9%)	1/16 (6.3%)	1/16 (6.3%)	0/13 (0.0%)	0/15 (0.0%)	0/9 (0.0%)
	Time-to-First	554	481	607	517	517	534
	Poly-K P-Value	0.205	0.473	0.320	0.548N	0.356	0.239
	Severity Profile	0 0 2 0	0 0 3 0	0 1 1 2	0 1 0 0	0 2 2 0	0 0 4 0
	JT/SW P-Value	0.233	0.315	0.225	0.479	0.279	0.234
	RTE P-Value	0.234	0.328	0.170	0.321N	0.222	0.167
Prostate, Ventral Lobe * Fibrosis	Simple Incidence	17/48 (35.4%)	10/47 (21.3%)	12/47 (25.5%)	10/50 (20.0%)	12/49 (24.5%)	8/45 (17.8%)
	Poly-K Incidence	17/39.3 (43.2%)	10/35.8 (28.0%)	12/36.3 (33.1%)	10/34.2 (29.2%)	12/38.3 (31.4%)	8/29.4 (27.2%)
	Terminal Incidence	6/17 (35.3%)	3/16 (18.8%)	3/16 (18.8%)	2/13 (15.4%)	5/15 (33.3%)	3/9 (33.3%)
	Time-to-First	483	395	582	498	432	480
	Poly-K P-Value	0.121N	0.120N	0.245N	0.151N	0.192N	0.126N
	Severity Profile	2 9 3 3	0 7 0 3	3 5 0 4	1 3 3 3	3 7 2 0	0 1 4 3
	JT/SW P-Value	0.069N	0.076N	0.120N	0.070N	0.084N	0.056N
	RTE P-Value	0.071N	0.067N	0.136N	0.056N	0.078N	0.044N*

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 8. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Prostate, Ventral Lobe * Hyperplasia, Epithelium	Simple Incidence	17/48 (35.4%)	7/47 (14.9%)	17/47 (36.2%)	16/50 (32.0%)	14/49 (28.6%)	13/45 (28.9%)
	Poly-K Incidence	17/38.9 (43.7%)	7/32.9 (21.3%)	17/36.0 (47.2%)	16/35.7 (44.9%)	14/37.4 (37.4%)	13/30.2 (43.0%)
	Terminal Incidence	9/17 (52.9%)	6/16 (37.5%)	10/16 (62.5%)	4/13 (30.8%)	7/15 (46.7%)	5/9 (55.6%)
	Time-to-First	518	665	512	474	558	530
	Poly-K P-Value	0.357	0.034N*	0.468	0.554	0.368N	0.578N
	Severity Profile	0 12 3 2	2 3 1 1	4 8 3 2	4 9 1 2	1 13 0 0	1 10 0 2
	JT/SW P-Value	0.447N	0.009N** ¹	0.134N	0.192N	0.193N	0.215N
	RTE P-Value	0.447N	0.009N**	0.450N	0.253N	0.145N	0.197N
Prostate, Ventral Lobe * Infiltration Cellular, Lymphocyte	Simple Incidence	19/48 (39.6%)	17/47 (36.2%)	15/47 (31.9%)	16/50 (32.0%)	20/49 (40.8%)	18/45 (40.0%)
	Poly-K Incidence	19/39.2 (48.4%)	17/37.7 (45.1%)	15/38.4 (39.1%)	16/34.5 (46.4%)	20/40.9 (48.9%)	18/33.2 (54.3%)
	Terminal Incidence	9/17 (52.9%)	6/16 (37.5%)	5/16 (31.3%)	8/13 (61.5%)	7/15 (46.7%)	8/9 (88.9%)
	Time-to-First	483	395	404	468	432	121
	Poly-K P-Value	0.271	0.476N	0.268N	0.524N	0.575	0.391
	Severity Profile	9 7 2 1	11 3 0 3	10 1 0 4	8 5 2 1	14 5 1 0	11 3 2 2
	JT/SW P-Value	0.465	0.689	0.832	0.872	0.725	0.683
	RTE P-Value	0.463	0.310N	0.189N	0.215N	0.416N	0.469N
Prostate, Ventral Lobe * Inflammation, Suppurative	Simple Incidence	10/48 (20.8%)	9/47 (19.1%)	9/47 (19.1%)	8/50 (16.0%)	10/49 (20.4%)	9/45 (20.0%)
	Poly-K Incidence	10/36.8 (27.2%)	9/35.2 (25.6%)	9/37.3 (24.1%)	8/33.7 (23.8%)	10/38.0 (26.3%)	9/30.1 (29.9%)
	Terminal Incidence	6/17 (35.3%)	3/16 (18.8%)	1/16 (6.3%)	2/13 (15.4%)	4/15 (26.7%)	4/9 (44.4%)
	Time-to-First	605	395	393	506	498	358
	Poly-K P-Value	0.448	0.544N	0.485N	0.477N	0.570N	0.513
	Severity Profile	5 2 1 2	5 1 1 2	3 2 0 4	4 1 1 2	5 4 0 1	4 2 2 1
	JT/SW P-Value	0.460N	0.416N	0.517N	0.356N	0.480N	0.529N
	RTE P-Value	0.462N	0.416N	0.461N	0.281N	0.462N	0.464N
Prostate, Ventral Lobe * Mineralization	Simple Incidence	3/48 (6.3%)	2/47 (4.3%)	0/47 (0.0%)	2/50 (4.0%)	3/49 (6.1%)	4/45 (8.9%)
	Poly-K Incidence	3/35.5 (8.5%)	2/32.6 (6.1%)	0/34.1 (0.0%)	2/30.8 (6.5%)	3/35.9 (8.4%)	4/28.4 (14.1%)
	Terminal Incidence	3/17 (17.6%)	2/16 (12.5%)	0/16 (0.0%)	2/13 (15.4%)	2/15 (13.3%)	2/9 (22.2%)
	Time-to-First	723 (T)	725 (T)	----	723 (T)	706	480
	Poly-K P-Value	0.206	0.538N	0.124N	0.565N	0.659N	0.378
	Severity Profile	1 2 0 0	0 2 0 0	---	0 2 0 0	0 2 1 0	0 3 1 0
	JT/SW P-Value	0.190	0.660	0.920	0.833	0.634	0.359
	RTE P-Value	0.182	0.335N	0.109N	0.311N	0.495	0.265

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 8. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Seminal Vesicle * Atrophy	Simple Incidence	5/39 (12.8%)	6/43 (14.0%)	4/41 (9.8%)	5/47 (10.6%)	5/48 (10.4%)	3/42 (7.1%)
	Poly-K Incidence	5/31.9 (15.7%)	6/32.7 (18.3%)	4/31.3 (12.8%)	5/30.9 (16.2%)	5/37.5 (13.3%)	3/26.8 (11.2%)
	Terminal Incidence	1/17 (5.9%)	1/16 (6.3%)	1/16 (6.3%)	1/13 (7.7%)	0/15 (0.0%)	0/9 (0.0%)
	Time-to-First	616	395	516	517	517	534
	Poly-K P-Value	0.294N	0.520	0.512N	0.615	0.525N	0.453N
	Severity Profile	0 2 2 1	0 0 5 1	0 0 1 3	0 1 3 1	0 0 5 0	0 1 1 1
	JT/SW P-Value	0.174N	0.587N	0.461N	0.488N	0.491N	0.294N
	RTE P-Value	0.175N	0.414	0.378N	0.387N	0.373N	0.219N
Seminal Vesicle * Dilatation,Lumen	Simple Incidence	6/39 (15.4%)	4/43 (9.3%)	2/41 (4.9%)	3/47 (6.4%)	1/48 (2.1%)	4/42 (9.5%)
	Poly-K Incidence	6/31.6 (19.0%)	4/30.6 (13.1%)	2/30.5 (6.5%)	3/30.1 (10.0%)	1/35.3 (2.8%)	4/27.0 (14.8%)
	Terminal Incidence	3/17 (17.6%)	3/16 (18.8%)	1/16 (6.3%)	1/13 (7.7%)	1/15 (6.7%)	0/9 (0.0%)
	Time-to-First	599	558	587	510	723 (T)	480
	Poly-K P-Value	0.102N	0.384N	0.136N	0.258N	0.035N*	0.468N
	Severity Profile	0 1 4 1	0 1 2 1	0 1 0 1	0 1 1 1	0 1 0 0	0 2 1 1
	JT/SW P-Value	0.076N	0.202N	0.068N	0.072N	0.010N** ¹	0.058N
	RTE P-Value	0.074N	0.129N	0.034N*	0.056N	0.011N*	0.129N
Seminal Vesicle * Hyperplasia,Epithelium	Simple Incidence	5/39 (12.8%)	1/43 (2.3%)	4/41 (9.8%)	4/47 (8.5%)	4/48 (8.3%)	6/42 (14.3%)
	Poly-K Incidence	5/31.3 (16.0%)	1/30.3 (3.3%)	4/30.1 (13.3%)	4/29.8 (13.4%)	4/36.0 (11.1%)	6/26.7 (22.4%)
	Terminal Incidence	4/17 (23.5%)	0/16 (0.0%)	4/16 (25.0%)	3/13 (23.1%)	2/15 (13.3%)	3/9 (33.3%)
	Time-to-First	552	669	724 (T)	506	624	474
	Poly-K P-Value	0.232	0.103N	0.526N	0.532N	0.410N	0.386
	Severity Profile	0 1 4 0	0 0 0 1	0 2 2 0	0 1 3 0	0 2 2 0	0 1 4 1
	JT/SW P-Value	0.238	0.961	0.789	0.853	0.882	0.529
	RTE P-Value	0.261	0.060N	0.305N	0.245N	0.227N	0.399
Testes * Degeneration,Seminiferous Tubule	Simple Incidence	34/49 (69.4%)	33/48 (68.8%)	41/48 (85.4%)	36/50 (72.0%)	40/49 (81.6%)	27/45 (60.0%)
	Poly-K Incidence	34/43.7 (77.9%)	33/42.7 (77.3%)	41/45.2 (90.7%)	36/43.5 (82.8%)	40/45.8 (87.3%)	27/35.6 (75.8%)
	Terminal Incidence	14/17 (82.4%)	11/16 (68.8%)	15/16 (93.8%)	11/13 (84.6%)	13/15 (86.7%)	7/9 (77.8%)
	Time-to-First	448	395	393	399	426	294
	Poly-K P-Value	0.320	0.584N	0.062	0.363	0.160	0.524N
	Severity Profile	10 7 3 14	14 6 5 8	17 8 1 15	13 10 7 6	9 10 7 14	11 4 5 7
	JT/SW P-Value	0.395N	0.209N	0.582N	0.342N	0.688N	0.100N
	RTE P-Value	0.346N	0.199N	0.205	0.257N	0.098	0.076N
Testes * Polyarteritis	Simple Incidence	18/49 (36.7%)	11/48 (22.9%)	15/48 (31.3%)	14/50 (28.0%)	28/49 (57.1%)	16/45 (35.6%)
	Poly-K Incidence	18/38.8 (46.4%)	11/35.6 (30.9%)	15/38.0 (39.5%)	14/35.6 (39.3%)	28/41.8 (67.0%)	16/30.7 (52.2%)
	Terminal Incidence	9/17 (52.9%)	6/16 (37.5%)	6/16 (37.5%)	5/13 (38.5%)	9/15 (60.0%)	5/9 (55.6%)
	Time-to-First	552	395	512	403	432	474
	Poly-K P-Value	0.012 *	0.119N	0.347N	0.345N	0.038 *	0.400
	Severity Profile	7 5 5 1	1 7 3 0	6 4 1 4	6 4 3 1	4 9 6 9	4 7 3 2
	JT/SW P-Value	0.026 *	0.907	0.779	0.878	0.004 ** ¹	0.110
	RTE P-Value	0.029 *	0.103N	0.325N	0.181N	0.002 **	0.494

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 8. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Hematopoietic System							
Bone Marrow * Hyperplasia, Myeloid Cell	Simple Incidence	4/47 (8.5%)	4/47 (8.5%)	3/46 (6.5%)	4/50 (8.0%)	5/49 (10.2%)	5/45 (11.1%)
	Poly-K Incidence	4/36.8 (10.9%)	4/33.1 (12.1%)	3/35.6 (8.4%)	4/32.5 (12.3%)	5/37.9 (13.2%)	5/29.9 (16.7%)
	Terminal Incidence	1/17 (5.9%)	2/16 (12.5%)	0/16 (0.0%)	0/13 (0.0%)	1/15 (6.7%)	0/9 (0.0%)
	Time-to-First	483	650	512	468	482	445
	Poly-K P-Value	0.259	0.585	0.519N	0.575	0.520	0.369
	Severity Profile	0 1 2 1	0 0 0 4	0 0 0 3	0 0 2 2	0 0 2 3	0 0 1 4
	JT/SW P-Value	0.276	0.463	0.622	0.641	0.475	0.407
	RTE P-Value	0.277	0.460	0.404N	0.482N	0.367	0.303
Bone Marrow * Hypocellularity	Simple Incidence	0/47 (0.0%)	3/47 (6.4%)	2/46 (4.3%)	4/50 (8.0%)	2/49 (4.1%)	4/45 (8.9%)
	Poly-K Incidence	0/35.5 (0.0%)	3/33.7 (8.9%)	2/34.8 (5.7%)	4/31.8 (12.6%)	2/36.1 (5.5%)	4/28.7 (14.0%)
	Terminal Incidence	0/17 (0.0%)	0/16 (0.0%)	1/16 (6.3%)	2/13 (15.4%)	1/15 (6.7%)	0/9 (0.0%)
	Time-to-First	----	555	567	558	652	507
	Poly-K P-Value	0.057	0.108	0.232	0.046 *	0.240	0.035 *
	Severity Profile	---	0 0 1 2	0 0 1 1	0 0 4 0	0 0 2 0	0 0 4 0
	JT/SW P-Value	0.077	0.040 * ¹	0.097	0.042 * ¹	0.105	0.037 *
	RTE P-Value	0.076	0.060	0.172	0.043 *	0.174	0.045 *
Spleen * Hematopoietic Cell Proliferation	Simple Incidence	16/47 (34.0%)	17/47 (36.2%)	9/47 (19.1%)	13/49 (26.5%)	24/49 (49.0%)	12/45 (26.7%)
	Poly-K Incidence	16/38.6 (41.5%)	17/38.3 (44.4%)	9/37.9 (23.8%)	13/35.4 (36.7%)	24/42.2 (56.9%)	12/32.9 (36.5%)
	Terminal Incidence	4/17 (23.5%)	3/16 (18.8%)	1/16 (6.3%)	2/13 (15.4%)	5/15 (33.3%)	2/9 (22.2%)
	Time-to-First	605	395	477	403	465	294
	Poly-K P-Value	0.278	0.487	0.073N	0.426N	0.113	0.424N
	Severity Profile	3 5 2 6	2 6 6 3	2 2 2 3	8 0 2 3	8 9 3 4	1 7 2 2
	JT/SW P-Value	0.476N	0.558N	0.070N	0.110N	0.404N	0.260N
	RTE P-Value	0.428N	0.423	0.058N	0.131N	0.119	0.194N
Spleen * Hyperplasia, Lymphoid	Simple Incidence	1/47 (2.1%)	2/47 (4.3%)	3/47 (6.4%)	6/49 (12.2%)	6/49 (12.2%)	3/45 (6.7%)
	Poly-K Incidence	1/35.7 (2.8%)	2/33.1 (6.0%)	3/36.3 (8.3%)	6/32.5 (18.5%)	6/37.5 (16.0%)	3/27.9 (10.8%)
	Terminal Incidence	0/17 (0.0%)	1/16 (6.3%)	0/16 (0.0%)	0/13 (0.0%)	0/15 (0.0%)	0/9 (0.0%)
	Time-to-First	667	589	512	566	551	600
	Poly-K P-Value	0.026 *	0.473	0.310	0.039 *	0.061	0.220
	Severity Profile	0 1 0 0	0 0 1 1	0 3 0 0	0 5 1 0	0 6 0 0	0 3 0 0
	JT/SW P-Value	0.052	0.271	0.188	0.026 * ¹	0.039 * ¹	0.083
	RTE P-Value	0.057	0.327	0.218	0.027 *	0.039 *	0.206

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 8. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Spleen * Pigmentation	Simple Incidence	26/47 (55.3%)	25/47 (53.2%)	27/47 (57.4%)	21/49 (42.9%)	24/49 (49.0%)	22/45 (48.9%)
	Poly-K Incidence	26/41.0 (63.4%)	25/39.4 (63.5%)	27/40.5 (66.7%)	21/37.5 (56.0%)	24/41.8 (57.4%)	22/34.9 (63.0%)
	Terminal Incidence	12/17 (70.6%)	11/16 (68.8%)	14/16 (87.5%)	7/13 (53.8%)	8/15 (53.3%)	6/9 (66.7%)
	Time-to-First	392	349	477	403	432	294
	Poly-K P-Value	0.303N	0.595	0.468	0.319N	0.363N	0.586N
	Severity Profile	7 12 5 2	7 12 4 2	9 11 5 2	10 5 3 3	7 14 1 2	3 14 1 4
	JT/SW P-Value	0.196N	0.398N	0.535N	0.099N	0.170N	0.262N
	RTE P-Value	0.205N	0.399N	0.481	0.075N	0.207N	0.361N
Thymus * Atrophy	Simple Incidence	47/48 (97.9%)	45/48 (93.8%)	44/46 (95.7%)	43/47 (91.5%)	46/48 (95.8%)	38/42 (90.5%)
	Poly-K Incidence	47/47.4 (99.2%)	45/45.7 (98.6%)	44/44.9 (98.1%)	43/44.2 (97.3%)	46/46.4 (99.1%)	38/38.9 (97.6%)
	Terminal Incidence	17/17 (100.0%)	16/16 (100.0%)	15/15 (100.0%)	13/13 (100.0%)	15/15 (100.0%)	9/9 (100.0%)
	Time-to-First	392	395	477	343	432	358
	Poly-K P-Value	0.315N	0.886N	0.719N	0.556N	0.971N	0.654N
	Severity Profile	0 0 1 46	0 0 1 44	0 0 0 44	0 1 1 41	0 0 1 45	0 0 5 33
	JT/SW P-Value	0.012N*	0.196N	0.375N	0.067N	0.205N	0.003N**
	RTE P-Value	0.010N**	0.232N	0.474N	0.060N	0.357N	0.004N**
Integumentary System							
Mammary Gland * Degeneration,Alveolus	Simple Incidence	28/49 (57.1%)	25/48 (52.1%)	22/47 (46.8%)	31/50 (62.0%)	33/49 (67.3%)	23/45 (51.1%)
	Poly-K Incidence	28/42.9 (65.3%)	25/39.5 (63.3%)	22/40.5 (54.3%)	31/41.2 (75.2%)	33/42.4 (77.9%)	23/34.1 (67.4%)
	Terminal Incidence	8/17 (47.1%)	10/16 (62.5%)	7/16 (43.8%)	10/13 (76.9%)	12/15 (80.0%)	7/9 (77.8%)
	Time-to-First	541	425	477	343	432	474
	Poly-K P-Value	0.085	0.516N	0.202N	0.208	0.130	0.521
	Severity Profile	0 1 11 16	0 4 8 13	0 2 8 12	0 3 11 17	0 3 9 21	1 4 6 12
	JT/SW P-Value	0.327	0.770	0.886	0.479	0.188	0.563
	RTE P-Value	0.350	0.231N	0.141N	0.379	0.139	0.189N
Mammary Gland * Dilatation,Alveolus	Simple Incidence	15/49 (30.6%)	7/48 (14.6%)	6/47 (12.8%)	7/50 (14.0%)	6/49 (12.2%)	7/45 (15.6%)
	Poly-K Incidence	15/38.9 (38.6%)	7/36.2 (19.4%)	6/35.0 (17.2%)	7/31.7 (22.1%)	6/37.2 (16.1%)	7/29.1 (24.1%)
	Terminal Incidence	8/17 (47.1%)	0/16 (0.0%)	3/16 (18.8%)	4/13 (30.8%)	2/15 (13.3%)	2/9 (22.2%)
	Time-to-First	552	529	567	590	555	465
	Poly-K P-Value	0.054N	0.052N	0.032N*	0.102N	0.022N*	0.154N
	Severity Profile	0 11 4 0	0 4 1 2	0 3 3 0	0 4 3 0	0 5 1 0	0 5 2 0
	JT/SW P-Value	0.032N*	0.041N*	0.021N*	0.021N*	0.009N**	0.019N*
	RTE P-Value	0.033N*	0.023N*	0.013N*	0.018N*	0.009N**	0.029N*

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 8. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Mammary Gland * Dilatation,Duct	Simple Incidence	15/49 (30.6%)	9/48 (18.8%)	10/47 (21.3%)	10/50 (20.0%)	11/49 (22.4%)	12/45 (26.7%)
	Poly-K Incidence	15/38.9 (38.6%)	9/36.4 (24.7%)	10/35.9 (27.9%)	10/32.3 (31.0%)	11/38.0 (28.9%)	12/29.6 (40.5%)
	Terminal Incidence	7/17 (41.2%)	1/16 (6.3%)	3/16 (18.8%)	6/13 (46.2%)	2/15 (13.3%)	4/9 (44.4%)
	Time-to-First	599	529	567	558	555	465
	Poly-K P-Value	0.469	0.142N	0.225N	0.332N	0.251N	0.536
	Severity Profile	0 9 4 2	1 3 3 2	1 3 5 1	0 6 2 2	1 5 5 0	0 5 6 1
	JT/SW P-Value	0.416N	0.103N	0.152N	0.142N	0.167N	0.229N
	RTE P-Value	0.434N	0.100N	0.155N	0.111N	0.164N	0.363N
Mammary Gland * Galactocele	Simple Incidence	3/49 (6.1%)	1/48 (2.1%)	5/47 (10.6%)	1/50 (2.0%)	1/49 (2.0%)	0/45 (0.0%)
	Poly-K Incidence	3/36.9 (8.1%)	1/33.7 (3.0%)	5/34.7 (14.4%)	1/31.0 (3.2%)	1/35.7 (2.8%)	0/27.0 (0.0%)
	Terminal Incidence	1/17 (5.9%)	0/16 (0.0%)	3/16 (18.8%)	0/13 (0.0%)	0/15 (0.0%)	0/9 (0.0%)
	Time-to-First	636	671	638	668	704	----
	Poly-K P-Value	0.086N	0.337N	0.320	0.369N	0.315N	0.182N
Musculoskeletal System							
Bone, Femur * Fibrous Osteodystrophy	Simple Incidence	4/50 (8.0%)	1/48 (2.1%)	3/48 (6.3%)	1/50 (2.0%)	5/50 (10.0%)	2/46 (4.3%)
	Poly-K Incidence	4/37.9 (10.6%)	1/34.1 (2.9%)	3/36.2 (8.3%)	1/31.4 (3.2%)	5/37.8 (13.2%)	2/27.9 (7.2%)
	Terminal Incidence	0/17 (0.0%)	0/16 (0.0%)	0/16 (0.0%)	0/13 (0.0%)	0/15 (0.0%)	0/9 (0.0%)
	Time-to-First	605	481	516	517	517	593
	Poly-K P-Value	0.416	0.209N	0.525N	0.238N	0.498	0.485N
	Severity Profile	0 3 1 0	0 0 0 1	0 1 0 2	0 0 1 0	0 0 3 2	0 2 0 0
	JT/SW P-Value	0.474	0.901	0.717	0.909	0.402	0.694
	RTE P-Value	0.476	0.135N	0.375N	0.129N	0.302	0.220N
Nervous System							
Brain, Brain Stem * Compression	Simple Incidence	11/50 (22.0%)	10/48 (20.8%)	10/47 (21.3%)	10/50 (20.0%)	6/50 (12.0%)	8/46 (17.4%)
	Poly-K Incidence	11/39.5 (27.8%)	10/36.8 (27.2%)	10/36.7 (27.3%)	10/33.3 (30.1%)	6/37.3 (16.1%)	8/29.9 (26.8%)
	Terminal Incidence	4/17 (23.5%)	0/16 (0.0%)	3/16 (18.8%)	4/13 (30.8%)	1/15 (6.7%)	1/9 (11.1%)
	Time-to-First	552	529	477	558	555	465
	Poly-K P-Value	0.257N	0.577N	0.582N	0.520	0.164N	0.570N
	Severity Profile	1 5 3 2	0 5 3 2	2 2 2 4	0 8 1 1	1 1 1 3	3 1 2 2
	JT/SW P-Value	0.131N	0.464N	0.563N	0.471N	0.157N	0.250N
	RTE P-Value	0.139N	0.459N	0.491N	0.374N	0.119N	0.274N
Brain, Cerebrum * Dilatation,Ventricle	Simple Incidence	7/49 (14.3%)	7/48 (14.6%)	6/48 (12.5%)	4/50 (8.0%)	3/50 (6.0%)	2/46 (4.3%)
	Poly-K Incidence	7/38.9 (18.0%)	7/36.0 (19.5%)	6/36.7 (16.4%)	4/32.1 (12.4%)	3/37.0 (8.1%)	2/28.2 (7.1%)
	Terminal Incidence	1/17 (5.9%)	0/16 (0.0%)	0/16 (0.0%)	1/13 (7.7%)	0/15 (0.0%)	0/9 (0.0%)
	Time-to-First	483	529	477	588	555	617
	Poly-K P-Value	0.037N*	0.553	0.547N	0.378N	0.173N	0.179N
	Severity Profile	4 3 0 0	4 2 1 0	3 3 0 0	3 1 0 0	1 1 1 0	0 2 0 0
	JT/SW P-Value	0.016N*	0.524N	0.481N	0.211N	0.134N	0.077N
	RTE P-Value	0.018N*	0.474	0.391N	0.133N	0.101N	0.069N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 8. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Stop Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Urinary System							
Kidney * Cyst,Cortex	Simple Incidence	8/50 (16.0%)	14/48 (29.2%)	12/48 (25.0%)	12/50 (24.0%)	14/50 (28.0%)	10/45 (22.2%)
	Poly-K Incidence	8/39.5 (20.2%)	14/36.6 (38.2%)	12/39.0 (30.8%)	12/32.6 (36.8%)	14/39.9 (35.1%)	10/29.8 (33.6%)
	Terminal Incidence	1/17 (5.9%)	5/16 (31.3%)	1/16 (6.3%)	7/13 (53.8%)	5/15 (33.3%)	4/9 (44.4%)
	Time-to-First	392	449	495	566	432	480
	Poly-K P-Value	0.140	0.064	0.205	0.091	0.104	0.161
Kidney * Cyst,Renal Tubule	Simple Incidence	18/50 (36.0%)	12/48 (25.0%)	20/48 (41.7%)	21/50 (42.0%)	27/50 (54.0%)	18/45 (40.0%)
	Poly-K Incidence	18/40.7 (44.3%)	12/35.5 (33.8%)	20/41.5 (48.2%)	21/37.5 (56.0%)	27/43.0 (62.8%)	18/33.2 (54.3%)
	Terminal Incidence	8/17 (47.1%)	6/16 (37.5%)	5/16 (31.3%)	8/13 (61.5%)	8/15 (53.3%)	5/9 (55.6%)
	Time-to-First	392	574	404	403	432	121
	Poly-K P-Value	0.012 *	0.235N	0.443	0.195	0.059	0.257
Kidney * Hyperplasia,Transitional Epithelium	Simple Incidence	12/50 (24.0%)	9/48 (18.8%)	12/48 (25.0%)	12/50 (24.0%)	20/50 (40.0%)	10/45 (22.2%)
	Poly-K Incidence	12/40.0 (30.0%)	9/36.7 (24.5%)	12/37.2 (32.3%)	12/34.9 (34.4%)	20/40.6 (49.3%)	10/29.4 (34.0%)
	Terminal Incidence	4/17 (23.5%)	2/16 (12.5%)	4/16 (25.0%)	3/13 (23.1%)	7/15 (46.7%)	3/9 (33.3%)
	Time-to-First	541	395	516	490	432	539
	Poly-K P-Value	0.043 *	0.388N	0.511	0.435	0.054	0.462
	Severity Profile	3 8 0 1	4 2 3 0	5 5 1 1	4 7 0 1	8 11 1 0	3 5 2 0
	JT/SW P-Value	0.153	0.737	0.558	0.616	0.064	0.305
	RTE P-Value	0.174	0.270N	0.482	0.480N	0.051	0.425N
Kidney * Infiltration Cellular,Polymorphonuclear	Simple Incidence	8/50 (16.0%)	5/48 (10.4%)	9/48 (18.8%)	8/50 (16.0%)	8/50 (16.0%)	5/45 (11.1%)
	Poly-K Incidence	8/38.2 (20.9%)	5/34.3 (14.6%)	9/36.2 (24.8%)	8/32.9 (24.3%)	8/37.2 (21.5%)	5/28.9 (17.3%)
	Terminal Incidence	3/17 (17.6%)	2/16 (12.5%)	4/16 (25.0%)	4/13 (30.8%)	3/15 (20.0%)	0/9 (0.0%)
	Time-to-First	552	584	534	443	551	445
	Poly-K P-Value	0.485	0.346N	0.449	0.477	0.587	0.476N
	Severity Profile	4 4 0 0	4 1 0 0	7 0 0 2	5 2 1 0	2 4 2 0	1 4 0 0
	JT/SW P-Value	0.468N	0.189N	0.469N	0.536N	0.591N	0.369N
	RTE P-Value	0.459N	0.196N	0.371	0.492N	0.457	0.274N
Kidney * Mineralization	Simple Incidence	10/50 (20.0%)	2/48 (4.2%)	3/48 (6.3%)	2/50 (4.0%)	6/50 (12.0%)	3/45 (6.7%)
	Poly-K Incidence	10/39.4 (25.3%)	2/34.4 (5.8%)	3/35.7 (8.4%)	2/32.1 (6.2%)	6/38.2 (15.7%)	3/27.7 (10.8%)
	Terminal Incidence	2/17 (11.8%)	0/16 (0.0%)	0/16 (0.0%)	0/13 (0.0%)	0/15 (0.0%)	0/9 (0.0%)
	Time-to-First	552	481	587	498	517	593
	Poly-K P-Value	0.131N	0.022N*	0.047N*	0.031N*	0.219N	0.121N
	Severity Profile	2 1 2 5	0 1 1 0	0 1 0 2	0 0 2 0	0 0 1 5	0 1 0 2
	JT/SW P-Value	0.099N	0.008N**	0.009N**	0.002N**	0.014N*	0.015N*
	RTE P-Value	0.104N	0.004N**	0.011N*	0.003N**	0.106N	0.014N*

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 8. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Stop Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Kidney * Nephropathy	Simple Incidence	48/50 (96.0%)	45/48 (93.8%)	45/48 (93.8%)	48/50 (96.0%)	46/50 (92.0%)	39/45 (86.7%)
	Poly-K Incidence	48/48.9 (98.1%)	45/46.3 (97.1%)	45/46.0 (97.8%)	48/48.6 (98.8%)	46/47.2 (97.6%)	39/40.8 (95.5%)
	Terminal Incidence	17/17 (100.0%)	16/16 (100.0%)	16/16 (100.0%)	13/13 (100.0%)	15/15 (100.0%)	9/9 (100.0%)
	Time-to-First	47	349	477	343	432	121
	Poly-K P-Value	0.306N	0.674N	0.796N	0.797	0.759N	0.444N
	Severity Profile	4 8 11 25	7 10 6 22	7 3 11 24	4 10 12 22	1 3 7 35	5 11 4 19
	JT/SW P-Value	0.475	0.832	0.676	0.766	0.057	0.600
	RTE P-Value	0.467N	0.172N	0.416N	0.306N	0.055	0.061N

P-values for dose trend are presented in the “Control” column.

N indicates a negative trend or negative treatment comparison to control with corresponding lower-tail p-values.

¹ Nonsignificant SW test due to the assumption of monotonicity.

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 9. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Alimentary System							
Liver * Angiectasis	Simple Incidence	3/50 (6.0%)	4/48 (8.3%)	5/46 (10.9%)	5/49 (10.2%)	3/50 (6.0%)	8/46 (17.4%)
	Poly-K Incidence	3/34.6 (8.7%)	4/34.8 (11.5%)	5/29.5 (16.9%)	5/33.4 (15.0%)	3/29.0 (10.4%)	8/32.3 (24.8%)
	Terminal Incidence	2/16 (12.5%)	0/19 (0.0%)	2/14 (14.3%)	2/13 (15.4%)	2/10 (20.0%)	4/8 (50.0%)
	Time-to-First	594	548	524	556	719	523
	Poly-K P-Value	0.059	0.503	0.267	0.333	0.579	0.069
	Severity Profile	0 2 1 0	0 4 0 0	1 2 2 0	0 3 0 2	0 3 0 0	2 4 2 0
	JT/SW P-Value	0.095	0.339	0.235	0.271	0.391	0.042 *
	RTE P-Value	0.088	0.361	0.213	0.230	0.489N	0.040 *
Liver * Basophilic Focus	Simple Incidence	18/50 (36.0%)	23/48 (47.9%)	15/46 (32.6%)	18/49 (36.7%)	19/50 (38.0%)	18/46 (39.1%)
	Poly-K Incidence	18/40.1 (44.9%)	23/37.4 (61.6%)	15/32.8 (45.8%)	18/38.4 (46.9%)	19/35.8 (53.1%)	18/34.2 (52.6%)
	Terminal Incidence	5/16 (31.3%)	13/19 (68.4%)	4/14 (28.6%)	4/13 (30.8%)	3/10 (30.0%)	6/8 (75.0%)
	Time-to-First	488	505	514	261	448	532
	Poly-K P-Value	0.428	0.094	0.566	0.520	0.306	0.326
Liver * Clear Cell Focus	Simple Incidence	9/50 (18.0%)	9/48 (18.8%)	12/46 (26.1%)	10/49 (20.4%)	6/50 (12.0%)	7/46 (15.2%)
	Poly-K Incidence	9/36.7 (24.5%)	9/33.6 (26.8%)	12/31.4 (38.2%)	10/35.6 (28.1%)	6/30.3 (19.8%)	7/33.8 (20.7%)
	Terminal Incidence	4/16 (25.0%)	6/19 (31.6%)	5/14 (35.7%)	2/13 (15.4%)	3/10 (30.0%)	1/8 (12.5%)
	Time-to-First	496	615	507	498	470	485
	Poly-K P-Value	0.257N	0.522	0.162	0.470	0.432N	0.461N
Liver * Degeneration,Cystic	Simple Incidence	4/50 (8.0%)	3/48 (6.3%)	6/46 (13.0%)	3/49 (6.1%)	5/50 (10.0%)	1/46 (2.2%)
	Poly-K Incidence	4/34.9 (11.5%)	3/33.3 (9.0%)	6/29.8 (20.2%)	3/33.2 (9.0%)	5/29.6 (16.9%)	1/31.2 (3.2%)
	Terminal Incidence	2/16 (12.5%)	2/19 (10.5%)	2/14 (14.3%)	0/13 (0.0%)	2/10 (20.0%)	0/8 (0.0%)
	Time-to-First	620	606	549	607	594	637
	Poly-K P-Value	0.288N	0.525N	0.266	0.527N	0.396	0.210N
	Severity Profile	4 0 0 0	3 0 0 0	6 0 0 0	3 0 0 0	4 1 0 0	1 0 0 0
	JT/SW P-Value	0.240N	0.369N	0.694N	0.465N	0.650N	0.191N
	RTE P-Value	0.225N	0.373N	0.154	0.363N	0.343	0.128N
Liver * Fatty Change	Simple Incidence	19/50 (38.0%)	9/48 (18.8%)	15/46 (32.6%)	15/49 (30.6%)	8/50 (16.0%)	12/46 (26.1%)
	Poly-K Incidence	19/40.4 (47.1%)	9/35.5 (25.3%)	15/32.2 (46.6%)	15/35.8 (41.9%)	8/31.6 (25.3%)	12/33.5 (35.8%)
	Terminal Incidence	5/16 (31.3%)	2/19 (10.5%)	5/14 (35.7%)	4/13 (30.8%)	2/10 (20.0%)	2/8 (25.0%)
	Time-to-First	488	507	489	556	419	523
	Poly-K P-Value	0.183N	0.037N*	0.581N	0.408N	0.043N*	0.221N
	Severity Profile	3 6 8 2	1 4 3 1	2 7 6 0	1 5 8 1	2 3 2 1	1 5 5 1
	JT/SW P-Value	0.089N	0.018N* ¹	0.094N	0.152N	0.006N**	0.035N*
	RTE P-Value	0.107N	0.015N*	0.234N	0.228N	0.007N**	0.098N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 9. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Continuous Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Liver * Fibrosis,Biliary Tract	Simple Incidence	6/50 (12.0%)	10/48 (20.8%)	4/46 (8.7%)	6/49 (12.2%)	5/50 (10.0%)	5/46 (10.9%)
	Poly-K Incidence	6/34.8 (17.3%)	10/34.9 (28.7%)	4/28.9 (13.8%)	6/34.4 (17.4%)	5/30.5 (16.4%)	5/32.3 (15.5%)
	Terminal Incidence	4/16 (25.0%)	5/19 (26.3%)	2/14 (14.3%)	2/13 (15.4%)	2/10 (20.0%)	0/8 (0.0%)
	Time-to-First	625	550	505	542	473	515
	Poly-K P-Value	0.228N	0.193	0.490N	0.619	0.596N	0.554N
	Severity Profile	3 3 0 0	6 4 0 0	3 1 0 0	5 1 0 0	3 2 0 0	4 1 0 0
	JT/SW P-Value	0.178N	0.873N	0.362N	0.492N	0.488N	0.520N
	RTE P-Value	0.177N	0.100	0.296N	0.485N	0.372N	0.409N
Liver * Hepatodiaphragmatic Nodule	Simple Incidence	6/50 (12.0%)	4/48 (8.3%)	6/46 (13.0%)	2/49 (4.1%)	5/50 (10.0%)	2/46 (4.3%)
	Poly-K Incidence	6/35.3 (17.0%)	4/34.7 (11.5%)	6/28.7 (20.9%)	2/33.8 (5.9%)	5/30.0 (16.7%)	2/31.2 (6.4%)
	Terminal Incidence	4/16 (25.0%)	0/19 (0.0%)	3/14 (21.4%)	0/13 (0.0%)	2/10 (20.0%)	1/8 (12.5%)
	Time-to-First	488	540	621	261	425	615
	Poly-K P-Value	0.148N	0.377N	0.467	0.141N	0.619N	0.169N
Liver * Hyperplasia,Bile Duct	Simple Incidence	16/50 (32.0%)	18/48 (37.5%)	16/46 (34.8%)	18/49 (36.7%)	11/50 (22.0%)	9/46 (19.6%)
	Poly-K Incidence	16/37.8 (42.3%)	18/35.6 (50.5%)	16/32.5 (49.3%)	18/38.0 (47.4%)	11/32.6 (33.8%)	9/32.0 (28.1%)
	Terminal Incidence	8/16 (50.0%)	10/19 (52.6%)	8/14 (57.1%)	5/13 (38.5%)	4/10 (40.0%)	3/8 (37.5%)
	Time-to-First	431	524	309	498	289	637
	Poly-K P-Value	0.050N	0.311	0.359	0.413	0.304N	0.152N
	Severity Profile	7 6 3 0	7 8 3 0	7 6 3 0	7 8 3 0	2 3 6 0	5 3 0 1
	JT/SW P-Value	0.043N*	0.722N	0.697N	0.777N	0.318N	0.118N
	RTE P-Value	0.039N*	0.274	0.388	0.300	0.225N	0.088N
Liver * Infiltration Cellular,Mononuclear Cell	Simple Incidence	37/50 (74.0%)	28/48 (58.3%)	35/46 (76.1%)	29/49 (59.2%)	26/50 (52.0%)	24/46 (52.2%)
	Poly-K Incidence	37/44.3 (83.4%)	28/38.1 (73.6%)	35/38.7 (90.4%)	29/41.9 (69.1%)	26/38.7 (67.2%)	24/37.9 (63.3%)
	Terminal Incidence	16/16 (100.0%)	15/19 (78.9%)	14/14 (100.0%)	7/13 (53.8%)	8/10 (80.0%)	5/8 (62.5%)
	Time-to-First	431	84	434	377	419	43
	Poly-K P-Value	0.003N**	0.172N	0.227	0.070N	0.045N*	0.018N*
	Severity Profile	27 9 1 0	20 8 0 0	29 6 0 0	24 5 0 0	21 5 0 0	19 4 1 0
	JT/SW P-Value	0.004N**	0.078N	0.220N	0.040N*	0.009N**	0.012N*
	RTE P-Value	0.004N**	0.065N	0.399N	0.035N*	0.008N**	0.011N*
Liver * Necrosis,Hepatocyte	Simple Incidence	1/50 (2.0%)	2/48 (4.2%)	3/46 (6.5%)	2/49 (4.1%)	4/50 (8.0%)	3/46 (6.5%)
	Poly-K Incidence	1/34.7 (2.9%)	2/33.5 (6.0%)	3/29.6 (10.1%)	2/33.3 (6.0%)	4/29.9 (13.4%)	3/31.0 (9.7%)
	Terminal Incidence	0/16 (0.0%)	0/19 (0.0%)	1/14 (7.1%)	0/13 (0.0%)	1/10 (10.0%)	1/8 (12.5%)
	Time-to-First	564	550	138	596	536	709
	Poly-K P-Value	0.109	0.488	0.248	0.485	0.133	0.263
	Severity Profile	1 0 0 0	1 1 0 0	2 0 1 0	1 0 0 1	2 0 1 1	0 1 0 2
	JT/SW P-Value	0.103	0.264	0.158	0.262	0.104	0.155
	RTE P-Value	0.110	0.315	0.196	0.316	0.088	0.135

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 9. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Continuous Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Liver * Tension Lipidosis	Simple Incidence	5/50 (10.0%)	7/48 (14.6%)	8/46 (17.4%)	6/49 (12.2%)	4/50 (8.0%)	10/46 (21.7%)
	Poly-K Incidence	5/35.9 (13.9%)	7/33.6 (20.8%)	8/30.9 (25.9%)	6/33.4 (18.0%)	4/29.7 (13.5%)	10/33.6 (29.7%)
	Terminal Incidence	2/16 (12.5%)	5/19 (26.3%)	2/14 (14.3%)	3/13 (23.1%)	1/10 (10.0%)	2/8 (25.0%)
	Time-to-First	496	625	482	602	612	510
	Poly-K P-Value	0.160	0.326	0.174	0.447	0.621N	0.089
	Severity Profile	0 1 1 3	0 3 1 3	0 1 1 6	0 2 1 3	0 1 3 0	1 2 1 6
	JT/SW P-Value	0.229	0.262	0.164	0.310	0.443	0.064
	RTE P-Value	0.219	0.275	0.133	0.384	0.358N	0.052
Liver * Vacuolization Cytoplasmic	Simple Incidence	11/50 (22.0%)	16/48 (33.3%)	14/46 (30.4%)	13/49 (26.5%)	15/50 (30.0%)	15/46 (32.6%)
	Poly-K Incidence	11/37.0 (29.8%)	16/36.1 (44.4%)	14/32.5 (43.1%)	13/36.9 (35.2%)	15/34.6 (43.4%)	15/37.0 (40.6%)
	Terminal Incidence	4/16 (25.0%)	10/19 (52.6%)	6/14 (42.9%)	3/13 (23.1%)	3/10 (30.0%)	3/8 (37.5%)
	Time-to-First	450	471	387	445	456	467
	Poly-K P-Value	0.272	0.137	0.173	0.398	0.160	0.225
	Severity Profile	4 7 0 0	5 11 0 0	5 8 1 0	6 5 2 0	9 6 0 0	11 4 0 0
	JT/SW P-Value	0.381	0.101	0.163	0.233	0.261	0.274
	RTE P-Value	0.392	0.097	0.166	0.313	0.252	0.215
Pancreas * Basophilic Focus	Simple Incidence	3/50 (6.0%)	6/48 (12.5%)	0/46 (0.0%)	1/49 (2.0%)	1/49 (2.0%)	2/46 (4.3%)
	Poly-K Incidence	3/35.0 (8.6%)	6/34.7 (17.3%)	0/27.7 (0.0%)	1/33.0 (3.0%)	1/29.5 (3.4%)	2/32.2 (6.2%)
	Terminal Incidence	0/16 (0.0%)	2/19 (10.5%)	0/14 (0.0%)	0/13 (0.0%)	0/10 (0.0%)	0/8 (0.0%)
	Time-to-First	569	524	---	561	425	467
	Poly-K P-Value	0.080N	0.232	0.162N	0.324N	0.366N	0.538N
Pancreas * Degeneration,Acinus	Simple Incidence	34/50 (68.0%)	34/48 (70.8%)	35/46 (76.1%)	29/49 (59.2%)	31/49 (63.3%)	36/46 (78.3%)
	Poly-K Incidence	34/43.4 (78.3%)	34/41.5 (81.9%)	35/41.2 (85.0%)	29/41.1 (70.6%)	31/40.9 (75.7%)	36/43.3 (83.1%)
	Terminal Incidence	15/16 (93.8%)	16/19 (84.2%)	11/14 (78.6%)	10/13 (76.9%)	7/10 (70.0%)	6/8 (75.0%)
	Time-to-First	450	84	387	445	419	43
	Poly-K P-Value	0.480N	0.437	0.282	0.264N	0.488N	0.373
	Severity Profile	5 16 8 5	7 16 5 6	9 14 9 3	8 13 5 3	8 14 2 7	13 9 9 5
	JT/SW P-Value	0.310N	0.487N	0.611N	0.093N	0.167N	0.341N
	RTE P-Value	0.328N	0.495N	0.415	0.077N	0.204N	0.386
Pancreas * Infiltration Cellular,Lymphocyte	Simple Incidence	35/50 (70.0%)	33/48 (68.8%)	31/46 (67.4%)	28/49 (57.1%)	28/49 (57.1%)	29/46 (63.0%)
	Poly-K Incidence	35/43.1 (81.1%)	33/40.1 (82.2%)	31/38.7 (80.0%)	28/40.5 (69.1%)	28/39.1 (71.7%)	29/41.5 (69.9%)
	Terminal Incidence	15/16 (93.8%)	16/19 (84.2%)	11/14 (78.6%)	10/13 (76.9%)	7/10 (70.0%)	5/8 (62.5%)
	Time-to-First	477	471	434	445	419	467
	Poly-K P-Value	0.027N*	0.569	0.570N	0.123N	0.194N	0.147N
	Severity Profile	16 17 2 0	18 12 2 1	15 13 3 0	19 6 3 0	18 6 4 0	16 9 4 0
	JT/SW P-Value	0.051N	0.350N	0.446N	0.042N* ¹	0.052N	0.103N
	RTE P-Value	0.055N	0.359N	0.394N	0.037N*	0.047N*	0.205N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 9. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Continuous Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Pancreas * Inflammation,Chronic Active	Simple Incidence	2/50 (4.0%)	4/48 (8.3%)	4/46 (8.7%)	1/49 (2.0%)	1/49 (2.0%)	3/46 (6.5%)
	Poly-K Incidence	2/34.8 (5.7%)	4/35.4 (11.3%)	4/29.3 (13.7%)	1/32.4 (3.1%)	1/28.8 (3.5%)	3/32.2 (9.3%)
	Terminal Incidence	1/16 (6.3%)	0/19 (0.0%)	1/14 (7.1%)	1/13 (7.7%)	0/10 (0.0%)	0/8 (0.0%)
	Time-to-First	506	84	507	723 (T)	701	569
	Poly-K P-Value	0.412N	0.342	0.256	0.525N	0.566N	0.463
	Severity Profile	0 2 0 0	1 3 0 0	1 2 1 0	0 1 0 0	0 1 0 0	2 0 1 0
	JT/SW P-Value	0.312N	0.809N	0.877N	0.428N	0.430N	0.592N
	RTE P-Value	0.311N	0.179	0.141	0.330N	0.330N	0.297
Pancreas * Lipomatosis	Simple Incidence	6/50 (12.0%)	4/48 (8.3%)	8/46 (17.4%)	6/49 (12.2%)	3/49 (6.1%)	7/46 (15.2%)
	Poly-K Incidence	6/35.6 (16.8%)	4/33.9 (11.8%)	8/30.3 (26.4%)	6/33.2 (18.1%)	3/29.7 (10.1%)	7/33.1 (21.1%)
	Terminal Incidence	2/16 (12.5%)	2/19 (10.5%)	2/14 (14.3%)	3/13 (23.1%)	1/10 (10.0%)	1/8 (12.5%)
	Time-to-First	506	548	528	624	425	525
	Poly-K P-Value	0.415	0.398N	0.257	0.574	0.334N	0.442
	Severity Profile	0 1 3 2	0 3 1 0	0 5 3 0	0 2 2 2	0 0 2 1	0 1 6 0
	JT/SW P-Value	0.449	0.759	0.308	0.472	0.676	0.439
	RTE P-Value	0.438	0.247N	0.258	0.497	0.176N	0.327
Pancreas * Pigmentation	Simple Incidence	11/50 (22.0%)	11/48 (22.9%)	14/46 (30.4%)	8/49 (16.3%)	3/49 (6.1%)	8/46 (17.4%)
	Poly-K Incidence	11/38.6 (28.5%)	11/34.4 (32.0%)	14/34.2 (40.9%)	8/34.9 (22.9%)	3/30.5 (9.8%)	8/34.0 (23.5%)
	Terminal Incidence	3/16 (18.8%)	8/19 (42.1%)	2/14 (14.3%)	2/13 (15.4%)	0/10 (0.0%)	1/8 (12.5%)
	Time-to-First	450	524	468	478	505	467
	Poly-K P-Value	0.062N	0.471	0.185	0.390N	0.050N*	0.415N
	Severity Profile	10 1 0 0	10 1 0 0	12 2 0 0	7 1 0 0	2 1 0 0	6 2 0 0
	JT/SW P-Value	0.039N*	0.543N	0.789N	0.330N	0.032N* ¹	0.146N
	RTE P-Value	0.041N*	0.454	0.137	0.242N	0.025N*	0.307N
Cardiovascular System							
Heart * Cardiomyopathy	Simple Incidence	35/50 (70.0%)	30/48 (62.5%)	24/46 (52.2%)	35/49 (71.4%)	33/50 (66.0%)	33/46 (71.7%)
	Poly-K Incidence	35/43.5 (80.6%)	30/39.0 (77.0%)	24/34.6 (69.4%)	35/42.3 (82.7%)	33/38.4 (85.9%)	33/39.4 (83.7%)
	Terminal Incidence	15/16 (93.8%)	17/19 (89.5%)	10/14 (71.4%)	13/13 (100.0%)	10/10 (100.0%)	8/8 (100.0%)
	Time-to-First	446	84	505	377	456	493
	Poly-K P-Value	0.140	0.444N	0.157N	0.510	0.334	0.459
	Severity Profile	24 10 1 0	18 7 4 1	18 5 1 0	25 9 1 0	24 7 1 1	23 9 0 1
	JT/SW P-Value	0.395	0.569	0.902	0.610	0.734	0.593
	RTE P-Value	0.388	0.410N	0.038N*	0.494	0.314N	0.451

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 9. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Endocrine System							
Adrenal Cortex * Angiectasis	Simple Incidence	9/50 (18.0%)	8/48 (16.7%)	6/45 (13.3%)	6/49 (12.2%)	6/49 (12.2%)	9/46 (19.6%)
	Poly-K Incidence	9/37.3 (24.1%)	8/35.6 (22.5%)	6/30.9 (19.4%)	6/34.1 (17.6%)	6/31.3 (19.2%)	9/32.9 (27.3%)
	Terminal Incidence	2/16 (12.5%)	3/19 (15.8%)	0/14 (0.0%)	1/13 (7.7%)	0/10 (0.0%)	2/8 (25.0%)
	Time-to-First	496	507	309	596	425	569
	Poly-K P-Value	0.503	0.546N	0.431N	0.349N	0.420N	0.486
	Severity Profile	0 4 3 2	0 4 3 1	0 5 1 0	0 5 1 0	0 3 0 3	1 6 2 0
	JT/SW P-Value	0.375N	0.417N	0.271N	0.225N	0.255N	0.366N
	RTE P-Value	0.391N	0.415N	0.226N	0.178N	0.213N	0.483
Adrenal Cortex * Degeneration,Cystic	Simple Incidence	31/50 (62.0%)	30/48 (62.5%)	27/45 (60.0%)	31/49 (63.3%)	29/49 (59.2%)	31/46 (67.4%)
	Poly-K Incidence	31/42.0 (73.8%)	30/40.2 (74.6%)	27/35.5 (76.1%)	31/40.1 (77.4%)	29/36.8 (78.9%)	31/38.9 (79.8%)
	Terminal Incidence	13/16 (81.3%)	13/19 (68.4%)	11/14 (78.6%)	13/13 (100.0%)	8/10 (80.0%)	7/8 (87.5%)
	Time-to-First	450	497	387	498	448	467
	Poly-K P-Value	0.200	0.573	0.514	0.445	0.378	0.336
	Severity Profile	3 10 8 10	3 9 6 12	6 5 4 12	5 7 5 14	8 5 4 12	4 13 6 8
	JT/SW P-Value	0.440N	0.592N	0.546N	0.677N	0.474N	0.575N
	RTE P-Value	0.433N	0.413	0.456N	0.374	0.352N	0.472
Adrenal Cortex * Hyperplasia	Simple Incidence	7/50 (14.0%)	7/48 (14.6%)	2/45 (4.4%)	3/49 (6.1%)	2/49 (4.1%)	5/46 (10.9%)
	Poly-K Incidence	7/36.7 (19.1%)	7/33.5 (20.9%)	2/28.3 (7.1%)	3/33.3 (9.0%)	2/28.8 (6.9%)	5/32.9 (15.2%)
	Terminal Incidence	2/16 (12.5%)	6/19 (31.6%)	1/14 (7.1%)	1/13 (7.7%)	1/10 (10.0%)	0/8 (0.0%)
	Time-to-First	450	548	541	582	701	523
	Poly-K P-Value	0.125N	0.543	0.150N	0.191N	0.145N	0.455N
	Severity Profile	3 3 1 0	6 1 0 0	1 1 0 0	1 2 0 0	1 1 0 0	2 3 0 0
	JT/SW P-Value	0.089N	0.481N	0.077N	0.088N	0.047N* ¹	0.122N
	RTE P-Value	0.105N	0.497N	0.047N*	0.086N	0.041N*	0.292N
Adrenal Cortex * Hypertrophy	Simple Incidence	5/50 (10.0%)	2/48 (4.2%)	2/45 (4.4%)	3/49 (6.1%)	4/49 (8.2%)	3/46 (6.5%)
	Poly-K Incidence	5/34.9 (14.3%)	2/33.6 (6.0%)	2/28.5 (7.0%)	3/33.5 (8.9%)	4/29.8 (13.4%)	3/32.1 (9.4%)
	Terminal Incidence	3/16 (18.8%)	0/19 (0.0%)	0/14 (0.0%)	0/13 (0.0%)	2/10 (20.0%)	0/8 (0.0%)
	Time-to-First	569	581	549	580	465	526
	Poly-K P-Value	0.493N	0.227N	0.301N	0.376N	0.602N	0.401N
	Severity Profile	1 3 1 0	1 0 1 0	1 0 1 0	1 1 1 0	1 2 1 0	2 0 1 0
	JT/SW P-Value	0.434N	0.133N	0.152N	0.190N	0.264N	0.283N
	RTE P-Value	0.444N	0.138N	0.157N	0.220N	0.357N	0.242N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 9. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Continuous Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Adrenal Cortex * Vacuolization Cytoplasmic	Simple Incidence	3/50 (6.0%)	6/48 (12.5%)	1/45 (2.2%)	5/49 (10.2%)	2/49 (4.1%)	4/46 (8.7%)
	Poly-K Incidence	3/34.2 (8.8%)	6/34.0 (17.7%)	1/28.1 (3.6%)	5/32.8 (15.2%)	2/29.2 (6.9%)	4/31.6 (12.7%)
	Terminal Incidence	3/16 (18.8%)	4/19 (21.1%)	0/14 (0.0%)	3/13 (23.1%)	1/10 (10.0%)	2/8 (25.0%)
	Time-to-First	725 (T)	550	615	669	594	542
	Poly-K P-Value	0.523N	0.232	0.376N	0.330	0.573N	0.456
	Severity Profile	1 2 0 0	2 4 0 0	1 0 0 0	1 3 1 0	2 0 0 0	0 3 0 1
	JT/SW P-Value	0.461N	0.866N	0.274N	0.653N	0.449N	0.679N
	RTE P-Value	0.468N	0.105	0.236N	0.175	0.345N	0.288
Adrenal Medulla * Hyperplasia	Simple Incidence	8/50 (16.0%)	7/48 (14.6%)	3/46 (6.5%)	4/49 (8.2%)	0/49 (0.0%)	4/46 (8.7%)
	Poly-K Incidence	8/35.8 (22.3%)	7/33.4 (20.9%)	3/28.9 (10.4%)	4/33.6 (11.9%)	0/28.7 (0.0%)	4/32.2 (12.4%)
	Terminal Incidence	4/16 (25.0%)	6/19 (31.6%)	0/14 (0.0%)	1/13 (7.7%)	0/10 (0.0%)	0/8 (0.0%)
	Time-to-First	569	570	581	561	----	526
	Poly-K P-Value	0.017N*	0.562N	0.171N	0.199N	0.008N**	0.223N
	Severity Profile	7 0 1 0	5 1 1 0	1 2 0 0	3 0 0 1	---	1 1 2 0
	JT/SW P-Value	0.013N*	0.441N	0.111N	0.125N	0.004N**	0.033N*
	RTE P-Value	0.014N*	0.417N	0.065N	0.104N	0.006N**	0.131N
Parathyroid Gland * Hyperplasia	Simple Incidence	4/50 (8.0%)	6/48 (12.5%)	3/45 (6.7%)	5/47 (10.6%)	3/50 (6.0%)	6/45 (13.3%)
	Poly-K Incidence	4/35.5 (11.3%)	6/34.6 (17.3%)	3/28.4 (10.5%)	5/33.3 (15.0%)	3/29.6 (10.1%)	6/31.5 (19.1%)
	Terminal Incidence	1/16 (6.3%)	2/19 (10.5%)	1/14 (7.1%)	0/13 (0.0%)	1/10 (10.0%)	1/8 (12.5%)
	Time-to-First	477	505	482	513	622	569
	Poly-K P-Value	0.345	0.349	0.622N	0.459	0.600N	0.290
	Severity Profile	2 2 0 0	2 3 1 0	1 2 0 0	2 2 0 1	2 1 0 0	2 2 1 1
	JT/SW P-Value	0.381	0.220	0.448	0.405	0.552	0.234
	RTE P-Value	0.367	0.195	0.420N	0.319	0.364N	0.162
Pituitary Gland * Angiectasis	Simple Incidence	10/50 (20.0%)	8/48 (16.7%)	4/46 (8.7%)	9/49 (18.4%)	9/49 (18.4%)	9/46 (19.6%)
	Poly-K Incidence	10/37.5 (26.7%)	8/35.4 (22.6%)	4/29.1 (13.7%)	9/34.8 (25.9%)	9/31.3 (28.8%)	9/32.2 (27.9%)
	Terminal Incidence	3/16 (18.8%)	2/19 (10.5%)	1/14 (7.1%)	2/13 (15.4%)	3/10 (30.0%)	3/8 (37.5%)
	Time-to-First	477	497	482	561	448	515
	Poly-K P-Value	0.330	0.446N	0.160N	0.577N	0.532	0.563
	Severity Profile	0 1 1 8	0 0 0 8	0 0 0 4	0 0 2 7	0 2 2 5	0 1 1 7
	JT/SW P-Value	0.441	0.632	0.889	0.710	0.747	0.677
	RTE P-Value	0.432	0.360N	0.083N	0.415N	0.376N	0.474N
Pituitary Gland * Cyst,Pars Distalis	Simple Incidence	9/50 (18.0%)	2/48 (4.2%)	7/46 (15.2%)	10/49 (20.4%)	3/49 (6.1%)	2/46 (4.3%)
	Poly-K Incidence	9/37.0 (24.3%)	2/33.2 (6.0%)	7/28.8 (24.3%)	10/35.2 (28.4%)	3/29.6 (10.1%)	2/31.7 (6.3%)
	Terminal Incidence	2/16 (12.5%)	1/19 (5.3%)	5/14 (35.7%)	3/13 (23.1%)	1/10 (10.0%)	0/8 (0.0%)
	Time-to-First	446	643	528	542	505	542
	Poly-K P-Value	0.102N	0.034N*	0.615	0.448	0.118N	0.041N*

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 9. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Continuous Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Pituitary Gland * Hyperplasia,Pars Distalis	Simple Incidence	27/50 (54.0%)	22/48 (45.8%)	32/46 (69.6%)	26/49 (53.1%)	29/49 (59.2%)	23/46 (50.0%)
	Poly-K Incidence	27/43.6 (61.9%)	22/40.2 (54.7%)	32/40.6 (78.9%)	26/44.2 (58.8%)	29/42.7 (68.0%)	23/39.7 (57.9%)
	Terminal Incidence	9/16 (56.3%)	7/19 (36.8%)	10/14 (71.4%)	3/13 (23.1%)	5/10 (50.0%)	4/8 (50.0%)
	Time-to-First	431	321	309	261	289	467
	Poly-K P-Value	0.515N	0.320N	0.056	0.466N	0.350	0.437N
	Severity Profile	0 3 12 12	1 2 5 14	0 4 12 16	1 5 7 13	3 10 4 12	1 6 6 10
	JT/SW P-Value	0.257N	0.342N	0.794N	0.563N	0.571N	0.354N
	RTE P-Value	0.253N	0.321N	0.059	0.441N	0.444N	0.262N
Thyroid Gland * Hyperplasia,C-Cell	Simple Incidence	22/50 (44.0%)	17/48 (35.4%)	22/46 (47.8%)	18/49 (36.7%)	20/50 (40.0%)	17/46 (37.0%)
	Poly-K Incidence	22/40.7 (54.0%)	17/37.3 (45.5%)	22/36.0 (61.1%)	18/38.4 (46.9%)	20/35.9 (55.8%)	17/36.6 (46.4%)
	Terminal Incidence	8/16 (50.0%)	8/19 (42.1%)	7/14 (50.0%)	5/13 (38.5%)	4/10 (40.0%)	1/8 (12.5%)
	Time-to-First	450	505	387	445	419	493
	Poly-K P-Value	0.372N	0.293N	0.336	0.335N	0.531	0.322N
	Severity Profile	11 9 2 0	12 3 2 0	13 7 2 0	11 7 0 0	8 10 2 0	7 8 2 0
	JT/SW P-Value	0.406N	0.136N	0.388N	0.222N	0.368N	0.385N
	RTE P-Value	0.407N	0.135N	0.413	0.175N	0.403N	0.291N
Thyroid Gland * Hyperplasia,Follicular Cell	Simple Incidence	1/50 (2.0%)	6/48 (12.5%)	4/46 (8.7%)	3/49 (6.1%)	1/50 (2.0%)	4/46 (8.7%)
	Poly-K Incidence	1/34.2 (2.9%)	6/34.1 (17.6%)	4/30.1 (13.3%)	3/33.3 (9.0%)	1/29.1 (3.4%)	4/32.9 (12.2%)
	Terminal Incidence	1/16 (6.3%)	2/19 (10.5%)	0/14 (0.0%)	0/13 (0.0%)	0/10 (0.0%)	0/8 (0.0%)
	Time-to-First	726 (T)	540	505	582	679	526
	Poly-K P-Value	0.494	0.051	0.137	0.294	0.725	0.163
	Severity Profile	0 1 0 0	0 2 4 0	0 2 1 1	0 2 1 0	0 0 0 1	0 2 2 0
	JT/SW P-Value	0.497N	0.979N	0.945N	0.887N	0.652N	0.879N
	RTE P-Value	0.494N	0.015 *	0.095	0.205	0.485	0.102
Thyroid Gland * Ultimobranchial Cyst	Simple Incidence	8/50 (16.0%)	2/48 (4.2%)	6/46 (13.0%)	3/49 (6.1%)	4/50 (8.0%)	7/46 (15.2%)
	Poly-K Incidence	8/36.4 (22.0%)	2/33.5 (6.0%)	6/30.2 (19.9%)	3/33.3 (9.0%)	4/30.2 (13.3%)	7/32.8 (21.4%)
	Terminal Incidence	4/16 (25.0%)	1/19 (5.3%)	2/14 (14.3%)	1/13 (7.7%)	1/10 (10.0%)	2/8 (25.0%)
	Time-to-First	431	534	387	596	521	485
	Poly-K P-Value	0.484	0.055N	0.539N	0.120N	0.273N	0.594N
Genital System							
Ovary * Atrophy	Simple Incidence	47/50 (94.0%)	45/48 (93.8%)	44/46 (95.7%)	46/49 (93.9%)	45/50 (90.0%)	46/46 (100.0%)
	Poly-K Incidence	47/48.7 (96.5%)	45/45.1 (99.8%)	44/44.2 (99.5%)	46/47.0 (97.9%)	45/45.8 (98.3%)	46/46.0 (100.0%)
	Terminal Incidence	16/16 (100.0%)	19/19 (100.0%)	14/14 (100.0%)	13/13 (100.0%)	10/10 (100.0%)	8/8 (100.0%)
	Time-to-First	431	321	309	377	419	43
	Poly-K P-Value	0.168	0.300	0.366	0.611	0.563	0.271
	Severity Profile	0 24 15 8	1 27 9 8	1 25 8 10	0 27 11 8	0 26 7 12	0 23 12 11
	JT/SW P-Value	0.202	0.801	0.698	0.778	0.803	0.247
	RTE P-Value	0.189	0.206N	0.395N	0.310N	0.319N	0.188

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 9. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Continuous Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Ovary * Cyst	Simple Incidence	4/50 (8.0%)	4/48 (8.3%)	4/46 (8.7%)	9/49 (18.4%)	2/50 (4.0%)	4/46 (8.7%)
	Poly-K Incidence	4/34.2 (11.7%)	4/33.8 (11.8%)	4/28.8 (13.9%)	9/34.3 (26.2%)	2/29.2 (6.8%)	4/31.1 (12.9%)
	Terminal Incidence	3/16 (18.8%)	2/19 (10.5%)	2/14 (14.3%)	3/13 (23.1%)	1/10 (10.0%)	1/8 (12.5%)
	Time-to-First	720	581	309	596	644	701
	Poly-K P-Value	0.442	0.640	0.548	0.104	0.410N	0.593
Ovary * Cyst,Follicle	Simple Incidence	3/50 (6.0%)	3/48 (6.3%)	2/46 (4.3%)	7/49 (14.3%)	6/50 (12.0%)	4/46 (8.7%)
	Poly-K Incidence	3/35.7 (8.4%)	3/33.4 (9.0%)	2/28.9 (6.9%)	7/34.5 (20.3%)	6/30.8 (19.5%)	4/32.3 (12.4%)
	Terminal Incidence	0/16 (0.0%)	2/19 (10.5%)	0/14 (0.0%)	2/13 (15.4%)	3/10 (30.0%)	1/8 (12.5%)
	Time-to-First	538	570	482	542	448	530
	Poly-K P-Value	0.106	0.634	0.597N	0.135	0.167	0.444
Ovary * Hyperplasia,Sertoliform	Simple Incidence	4/50 (8.0%)	5/48 (10.4%)	1/46 (2.2%)	5/49 (10.2%)	6/50 (12.0%)	4/46 (8.7%)
	Poly-K Incidence	4/34.6 (11.6%)	5/33.5 (14.9%)	1/28.3 (3.5%)	5/33.3 (15.0%)	6/30.0 (20.0%)	4/31.3 (12.8%)
	Terminal Incidence	2/16 (12.5%)	4/19 (21.1%)	0/14 (0.0%)	3/13 (23.1%)	2/10 (20.0%)	1/8 (12.5%)
	Time-to-First	667	550	549	602	561	665
	Poly-K P-Value	0.311	0.478	0.241N	0.475	0.275	0.589
	Severity Profile	4 0 0 0	3 1 1 0	1 0 0 0	3 2 0 0	3 1 2 0	3 0 1 0
	JT/SW P-Value	0.296	0.320	0.697	0.413	0.285	0.427
	RTE P-Value	0.301	0.318	0.161N	0.334	0.194	0.438
Uterus * Atrophy	Simple Incidence	7/50 (14.0%)	8/48 (16.7%)	4/45 (8.9%)	9/49 (18.4%)	4/48 (8.3%)	6/46 (13.0%)
	Poly-K Incidence	7/35.6 (19.7%)	8/34.4 (23.3%)	4/29.6 (13.5%)	9/34.8 (25.9%)	4/29.8 (13.4%)	6/31.5 (19.1%)
	Terminal Incidence	1/16 (6.3%)	4/19 (21.1%)	1/14 (7.1%)	4/13 (30.8%)	2/10 (20.0%)	3/8 (37.5%)
	Time-to-First	620	497	489	580	489	580
	Poly-K P-Value	0.401N	0.469	0.370N	0.366	0.366N	0.600N
	Severity Profile	0 0 7 0	0 0 5 3	0 1 3 0	0 2 5 2	0 0 3 1	0 0 6 0
	JT/SW P-Value	0.301N	0.686N	0.270N	0.601N	0.291N	0.435N
	RTE P-Value	0.303N	0.311	0.225N	0.263	0.219N	0.446N
Uterus * Dilatation,Lumen	Simple Incidence	2/50 (4.0%)	2/48 (4.2%)	3/45 (6.7%)	4/49 (8.2%)	5/48 (10.4%)	6/46 (13.0%)
	Poly-K Incidence	2/35.6 (5.6%)	2/33.5 (6.0%)	3/28.5 (10.5%)	4/34.5 (11.6%)	5/30.1 (16.6%)	6/33.0 (18.2%)
	Terminal Incidence	0/16 (0.0%)	1/19 (5.3%)	1/14 (7.1%)	0/13 (0.0%)	1/10 (10.0%)	0/8 (0.0%)
	Time-to-First	446	550	610	261	562	467
	Poly-K P-Value	0.020 *	0.673	0.398	0.319	0.147	0.103
	Severity Profile	0 0 0 2	0 0 0 2	0 0 0 3	0 0 1 3	0 0 0 5	0 0 1 5
	JT/SW P-Value	0.023 *	0.483	0.328	0.246	0.132	0.065
	RTE P-Value	0.023 *	0.488	0.313	0.227	0.112	0.059

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 9. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Continuous Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Uterus * Hyperplasia,Cystic,Endometrium	Simple Incidence	30/50 (60.0%)	20/48 (41.7%)	26/45 (57.8%)	23/49 (46.9%)	22/48 (45.8%)	26/46 (56.5%)
	Poly-K Incidence	30/41.9 (71.6%)	20/40.1 (49.9%)	26/36.9 (70.4%)	23/40.6 (56.6%)	22/35.8 (61.4%)	26/39.2 (66.4%)
	Terminal Incidence	13/16 (81.3%)	6/19 (31.6%)	8/14 (57.1%)	4/13 (30.8%)	5/10 (50.0%)	4/8 (50.0%)
	Time-to-First	431	286	387	377	473	485
	Poly-K P-Value	0.478N	0.027N*	0.558N	0.097N	0.216N	0.385N
	Severity Profile	4 18 5 3	2 13 5 0	0 16 7 3	4 12 6 1	4 8 8 2	1 14 10 1
	JT/SW P-Value	0.441	0.958	0.430	0.801	0.873	0.581
	RTE P-Value	0.415	0.049N*	0.375	0.115N	0.162N	0.442
Uterus * Hyperplasia,Endometrium	Simple Incidence	10/50 (20.0%)	15/48 (31.3%)	12/45 (26.7%)	15/49 (30.6%)	15/48 (31.3%)	12/46 (26.1%)
	Poly-K Incidence	10/39.1 (25.6%)	15/36.4 (41.2%)	12/31.9 (37.6%)	15/37.1 (40.4%)	15/35.9 (41.8%)	12/36.2 (33.2%)
	Terminal Incidence	2/16 (12.5%)	8/19 (42.1%)	5/14 (35.7%)	5/13 (38.5%)	2/10 (20.0%)	1/8 (12.5%)
	Time-to-First	488	505	309	445	419	43
	Poly-K P-Value	0.248	0.108	0.196	0.120	0.099	0.315
	Severity Profile	2 8 0 0	5 8 2 0	2 8 2 0	6 7 0 2	10 5 0 0	2 7 1 2
	JT/SW P-Value	0.278	0.108	0.182	0.172	0.207	0.228
	RTE P-Value	0.289	0.116	0.206	0.140	0.196	0.208
Uterus * Metaplasia,Squamous	Simple Incidence	2/50 (4.0%)	4/48 (8.3%)	4/45 (8.9%)	1/49 (2.0%)	4/48 (8.3%)	6/46 (13.0%)
	Poly-K Incidence	2/35.7 (5.6%)	4/35.0 (11.4%)	4/29.5 (13.6%)	1/32.8 (3.0%)	4/31.1 (12.9%)	6/33.9 (17.7%)
	Terminal Incidence	0/16 (0.0%)	0/19 (0.0%)	1/14 (7.1%)	0/13 (0.0%)	0/10 (0.0%)	0/8 (0.0%)
	Time-to-First	431	471	539	624	470	485
	Poly-K P-Value	0.110	0.326	0.249	0.529N	0.272	0.110
	Severity Profile	1 1 0 0	2 2 0 0	1 2 0 1	1 0 0 0	1 3 0 0	4 1 1 0
	JT/SW P-Value	0.116	0.187	0.200	0.391	0.243	0.060
	RTE P-Value	0.119	0.208	0.162	0.351N	0.190	0.051
Vagina * Degeneration,Epithelium	Simple Incidence	1/49 (2.0%)	6/48 (12.5%)	3/45 (6.7%)	2/49 (4.1%)	6/50 (12.0%)	2/46 (4.3%)
	Poly-K Incidence	1/34.2 (2.9%)	6/35.0 (17.2%)	3/28.9 (10.4%)	2/33.0 (6.1%)	6/31.1 (19.3%)	2/32.1 (6.2%)
	Terminal Incidence	0/16 (0.0%)	1/19 (5.3%)	0/14 (0.0%)	1/13 (7.7%)	3/10 (30.0%)	0/8 (0.0%)
	Time-to-First	564	497	489	561	419	517
	Poly-K P-Value	0.401	0.055	0.244	0.487	0.038 *	0.477
	Severity Profile	0 0 1 0	0 2 3 1	0 1 2 0	0 1 1 0	0 3 2 1	0 2 0 0
	JT/SW P-Value	0.401	0.024 * ¹	0.090	0.158	0.039 * ¹	0.160
	RTE P-Value	0.424	0.022 *	0.221	0.351	0.032 *	0.345
Vagina * Hyperplasia,Epithelium	Simple Incidence	4/49 (8.2%)	5/48 (10.4%)	12/45 (26.7%)	10/49 (20.4%)	11/50 (22.0%)	12/46 (26.1%)
	Poly-K Incidence	4/35.2 (11.4%)	5/35.3 (14.2%)	12/33.7 (35.6%)	10/36.5 (27.4%)	11/33.4 (32.9%)	12/36.8 (32.6%)
	Terminal Incidence	2/16 (12.5%)	1/19 (5.3%)	2/14 (14.3%)	1/13 (7.7%)	2/10 (20.0%)	0/8 (0.0%)
	Time-to-First	431	471	434	478	470	43
	Poly-K P-Value	0.006 **	0.502	0.014 *	0.074	0.026 *	0.026 *
	Severity Profile	0 1 2 1	0 1 4 0	1 3 6 2	0 7 3 0	0 3 5 3	0 6 4 2
	JT/SW P-Value	0.007 **	0.360	0.007 **	0.031 *	0.038 *	0.019 *
	RTE P-Value	0.009 **	0.394	0.012 *	0.088	0.035 *	0.016 *

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 9. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Continuous Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Vagina * Infiltration Cellular,Polymorphonuclear	Simple Incidence	7/49 (14.3%)	2/48 (4.2%)	9/45 (20.0%)	3/49 (6.1%)	6/50 (12.0%)	6/46 (13.0%)
	Poly-K Incidence	7/36.3 (19.3%)	2/33.0 (6.1%)	9/31.8 (28.3%)	3/32.4 (9.2%)	6/32.7 (18.3%)	6/31.9 (18.8%)
	Terminal Incidence	2/16 (12.5%)	1/19 (5.3%)	3/14 (21.4%)	3/13 (23.1%)	0/10 (0.0%)	2/8 (25.0%)
	Time-to-First	495	699	387	724 (T)	425	517
	Poly-K P-Value	0.432	0.097N	0.276	0.199N	0.582N	0.602N
	Severity Profile	0 2 2 3	0 1 1 0	0 5 2 2	0 2 1 0	0 1 2 3	0 3 1 2
	JT/SW P-Value	0.467	0.960	0.277	0.750	0.770	0.748
	RTE P-Value	0.465	0.049N*	0.219	0.087N	0.368N	0.405N
Vagina * Mucification,Epithelium	Simple Incidence	46/49 (93.9%)	37/48 (77.1%)	34/45 (75.6%)	39/49 (79.6%)	34/50 (68.0%)	40/46 (87.0%)
	Poly-K Incidence	46/47.2 (97.4%)	37/42.0 (88.1%)	34/39.3 (86.6%)	39/45.2 (86.4%)	34/42.8 (79.4%)	40/43.6 (91.8%)
	Terminal Incidence	16/16 (100.0%)	17/19 (89.5%)	13/14 (92.9%)	10/13 (76.9%)	6/10 (60.0%)	8/8 (100.0%)
	Time-to-First	450	497	309	377	419	43
	Poly-K P-Value	0.055N	0.064N	0.025N*	0.033N*	0.002N**	0.182N
	Severity Profile	0 13 12 21	0 7 8 22	0 7 11 16	0 4 14 21	0 8 9 17	1 10 8 21
	JT/SW P-Value	0.219N	0.296N	0.123N	0.286N	0.035N* ¹	0.182N
	RTE P-Value	0.233N	0.286N	0.103N	0.367N	0.029N*	0.399N
Hematopoietic System							
Bone Marrow * Hypocellularity	Simple Incidence	2/50 (4.0%)	3/48 (6.3%)	1/46 (2.2%)	2/49 (4.1%)	2/49 (4.1%)	6/46 (13.0%)
	Poly-K Incidence	2/35.3 (5.7%)	3/34.0 (8.8%)	1/28.4 (3.5%)	2/32.8 (6.1%)	2/29.5 (6.8%)	6/32.0 (18.8%)
	Terminal Incidence	0/16 (0.0%)	1/19 (5.3%)	0/14 (0.0%)	1/13 (7.7%)	1/10 (10.0%)	1/8 (12.5%)
	Time-to-First	450	497	482	634	456	515
	Poly-K P-Value	0.068	0.482	0.576N	0.669	0.628	0.096
	Severity Profile	0 0 1 1	0 0 1 2	0 0 0 1	0 0 2 0	0 0 1 1	0 0 5 1
	JT/SW P-Value	0.085	0.304	0.552	0.596	0.618	0.037 *
	RTE P-Value	0.076	0.308	0.352N	0.497N	0.493	0.035 *
Spleen * Hematopoietic Cell Proliferation	Simple Incidence	28/50 (56.0%)	27/48 (56.3%)	29/46 (63.0%)	30/49 (61.2%)	30/50 (60.0%)	23/46 (50.0%)
	Poly-K Incidence	28/44.0 (63.7%)	27/39.8 (67.9%)	29/39.4 (73.6%)	30/41.7 (72.0%)	30/41.9 (71.6%)	23/40.3 (57.1%)
	Terminal Incidence	8/16 (50.0%)	12/19 (63.2%)	7/14 (50.0%)	8/13 (61.5%)	5/10 (50.0%)	2/8 (25.0%)
	Time-to-First	431	84	309	478	419	43
	Poly-K P-Value	0.372N	0.427	0.217	0.265	0.279	0.339N
	Severity Profile	5 12 6 5	1 12 8 6	3 14 8 4	3 13 8 6	5 13 7 5	4 7 7 5
	JT/SW P-Value	0.397N	0.707N	0.823N	0.867N	0.784N	0.541N
	RTE P-Value	0.388N	0.289	0.237	0.218	0.357	0.409N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 9. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Continuous Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Spleen * Pigmentation	Simple Incidence	32/50 (64.0%)	27/48 (56.3%)	28/46 (60.9%)	34/49 (69.4%)	35/50 (70.0%)	30/46 (65.2%)
	Poly-K Incidence	32/44.2 (72.5%)	27/41.6 (64.9%)	28/37.0 (75.6%)	34/44.0 (77.3%)	35/42.6 (82.1%)	30/40.7 (73.7%)
	Terminal Incidence	11/16 (68.8%)	10/19 (52.6%)	12/14 (85.7%)	12/13 (92.3%)	9/10 (90.0%)	6/8 (75.0%)
	Time-to-First	431	147	309	261	256	485
	Poly-K P-Value	0.133	0.291N	0.470	0.379	0.182	0.551
	Severity Profile	7 13 6 6	6 11 7 3	5 10 7 6	9 16 5 4	4 10 13 8	6 13 4 7
	JT/SW P-Value	0.099	0.788	0.575	0.610	0.102	0.283
	RTE P-Value	0.112	0.215N	0.484	0.491N	0.077	0.423
Thymus * Atrophy	Simple Incidence	47/50 (94.0%)	47/48 (97.9%)	43/44 (97.7%)	47/49 (95.9%)	47/49 (95.9%)	44/45 (97.8%)
	Poly-K Incidence	47/49.3 (95.4%)	47/47.0 (100.0%)	43/43.2 (99.5%)	47/47.2 (99.6%)	47/47.1 (99.8%)	44/44.0 (100.0%)
	Terminal Incidence	16/16 (100.0%)	19/19 (100.0%)	14/14 (100.0%)	13/13 (100.0%)	10/10 (100.0%)	8/8 (100.0%)
	Time-to-First	431	84	309	445	419	467
	Poly-K P-Value	0.016 *	0.178	0.251	0.216	0.198	0.191
	Severity Profile	0 2 4 1	0 2 6 39	0 1 7 35	0 0 4 43	0 3 8 36	0 0 4 40
	JT/SW P-Value	0.334	0.492	0.608	0.262	0.669	0.219
	RTE P-Value	0.313	0.496	0.436N	0.206	0.156N	0.162
Integumentary System							
Mammary Gland * Atypical Focus	Simple Incidence	2/50 (4.0%)	7/48 (14.6%)	1/46 (2.2%)	5/49 (10.2%)	3/50 (6.0%)	3/46 (6.5%)
	Poly-K Incidence	2/34.4 (5.8%)	7/33.6 (20.9%)	1/28.2 (3.5%)	5/33.3 (15.0%)	3/29.7 (10.1%)	3/31.7 (9.5%)
	Terminal Incidence	1/16 (6.3%)	5/19 (26.3%)	0/14 (0.0%)	3/13 (23.1%)	2/10 (20.0%)	1/8 (12.5%)
	Time-to-First	672	621	581	561	456	517
	Poly-K P-Value	0.504N	0.067	0.569N	0.197	0.432	0.463
	Severity Profile	0 2 0 0	3 2 2 0	0 1 0 0	0 5 0 0	1 2 0 0	1 2 0 0
	JT/SW P-Value	0.436N	0.963N	0.430N	0.787N	0.780N	0.806N
	RTE P-Value	0.427N	0.024 *	0.364N	0.107	0.358	0.325
Mammary Gland * Dilatation,Alveolus	Simple Incidence	9/50 (18.0%)	14/48 (29.2%)	5/46 (10.9%)	7/49 (14.3%)	7/50 (14.0%)	11/46 (23.9%)
	Poly-K Incidence	9/36.0 (25.0%)	14/38.0 (36.8%)	5/30.9 (16.2%)	7/35.2 (19.9%)	7/32.3 (21.7%)	11/34.6 (31.8%)
	Terminal Incidence	5/16 (31.3%)	4/19 (21.1%)	0/14 (0.0%)	1/13 (7.7%)	0/10 (0.0%)	1/8 (12.5%)
	Time-to-First	477	497	468	478	470	485
	Poly-K P-Value	0.444N	0.192	0.277N	0.407N	0.486N	0.351
	Severity Profile	1 7 1 0	1 1 1 2 0	0 5 0 0	0 7 0 0	0 6 1 0	0 9 2 0
	JT/SW P-Value	0.412N	0.908N	0.229N	0.315N	0.351N	0.531N
	RTE P-Value	0.425N	0.068	0.192N	0.318N	0.320N	0.197

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 9. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Continuous Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Mammary Gland * Dilatation,Duct	Simple Incidence	15/50 (30.0%)	16/48 (33.3%)	7/46 (15.2%)	9/49 (18.4%)	9/50 (18.0%)	14/46 (30.4%)
	Poly-K Incidence	15/38.1 (39.4%)	16/39.4 (40.6%)	7/31.9 (22.0%)	9/35.7 (25.2%)	9/33.1 (27.2%)	14/36.4 (38.5%)
	Terminal Incidence	7/16 (43.8%)	3/19 (15.8%)	0/14 (0.0%)	2/13 (15.4%)	0/10 (0.0%)	1/8 (12.5%)
	Time-to-First	477	471	468	478	470	485
	Poly-K P-Value	0.260N	0.551	0.089N	0.138N	0.193N	0.564N
	Severity Profile	0 10 5 0	0 12 2 2	0 6 1 0	0 6 3 0	0 4 5 0	2 9 3 0
	JT/SW P-Value	0.182N	0.619N	0.049N* ¹	0.073N	0.087N	0.174N
	RTE P-Value	0.198N	0.364	0.034N*	0.089N	0.098N	0.449N
Mammary Gland * Hyperplasia,Lobular	Simple Incidence	43/50 (86.0%)	41/48 (85.4%)	30/46 (65.2%)	38/49 (77.6%)	40/50 (80.0%)	37/46 (80.4%)
	Poly-K Incidence	43/45.4 (94.7%)	41/42.5 (96.4%)	30/36.7 (81.8%)	38/43.7 (86.9%)	40/43.2 (92.6%)	37/43.4 (85.2%)
	Terminal Incidence	16/16 (100.0%)	19/19 (100.0%)	12/14 (85.7%)	11/13 (84.6%)	10/10 (100.0%)	6/8 (75.0%)
	Time-to-First	477	471	482	445	419	467
	Poly-K P-Value	0.041N*	0.573	0.027N*	0.130N	0.521N	0.099N
	Severity Profile	1 8 13 21	1 7 11 22	1 7 10 12	0 7 17 14	1 14 11 14	4 9 5 19
	JT/SW P-Value	0.058N	0.596N	0.012N* ¹	0.048N* ¹	0.051N	0.085N
	RTE P-Value	0.059N	0.419	0.008N**	0.113N	0.047N*	0.170N
Nervous System							
Brain, Brain Stem * Compression	Simple Incidence	14/50 (28.0%)	13/48 (27.1%)	7/46 (15.2%)	14/49 (28.6%)	13/50 (26.0%)	17/46 (37.0%)
	Poly-K Incidence	14/38.6 (36.2%)	13/36.4 (35.7%)	7/29.5 (23.7%)	14/36.8 (38.0%)	13/32.8 (39.6%)	17/34.3 (49.6%)
	Terminal Incidence	3/16 (18.8%)	5/19 (26.3%)	3/14 (21.4%)	3/13 (23.1%)	3/10 (30.0%)	3/8 (37.5%)
	Time-to-First	477	497	482	513	456	510
	Poly-K P-Value	0.098	0.578N	0.195N	0.532	0.481	0.169
	Severity Profile	1 3 4 6	3 4 2 4	5 0 2 0	2 5 3 4	2 3 5 3	2 5 5 5
	JT/SW P-Value	0.176	0.622	0.915	0.661	0.740	0.266
	RTE P-Value	0.166	0.373N	0.038N*	0.451N	0.348N	0.196
Brain, Cerebrum * Dilatation,Ventricle	Simple Incidence	7/50 (14.0%)	4/48 (8.3%)	2/46 (4.3%)	4/49 (8.2%)	6/50 (12.0%)	6/46 (13.0%)
	Poly-K Incidence	7/36.0 (19.5%)	4/34.6 (11.6%)	2/28.8 (7.0%)	4/33.3 (12.0%)	6/30.8 (19.5%)	6/31.9 (18.8%)
	Terminal Incidence	1/16 (6.3%)	0/19 (0.0%)	0/14 (0.0%)	2/13 (15.4%)	1/10 (10.0%)	1/8 (12.5%)
	Time-to-First	495	497	482	604	521	515
	Poly-K P-Value	0.383	0.276N	0.137N	0.300N	0.622N	0.596N
	Severity Profile	4 3 0 0	1 3 0 0	1 1 0 0	0 4 0 0	1 5 0 0	4 2 0 0
	JT/SW P-Value	0.405	0.795	0.946	0.916	0.742	0.722
	RTE P-Value	0.389	0.210N	0.073N	0.215N	0.404N	0.432N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 9. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Continuous Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Respiratory System							
Lung * Hyperplasia,Alveolar Epithelium	Simple Incidence	4/38 (10.5%)	2/32 (6.3%)	1/34 (2.9%)	1/39 (2.6%)	3/44 (6.8%)	0/42 (0.0%)
	Poly-K Incidence	4/22.8 (17.5%)	2/17.0 (11.8%)	1/15.7 (6.4%)	1/22.5 (4.4%)	3/24.4 (12.3%)	0/26.8 (0.0%)
	Terminal Incidence	2/4 (50.0%)	1/3 (33.3%)	1/2 (50.0%)	0/3 (0.0%)	0/4 (0.0%)	0/4 (0.0%)
	Time-to-First	625	714	724 (T)	708	489	----
	Poly-K P-Value	0.027N*	0.480N	0.300N	0.171N	0.461N	0.037N*
	Severity Profile	2 2 0 0	1 1 0 0	0 1 0 0	0 1 0 0	1 2 0 0	---
	JT/SW P-Value	0.041N*	0.264N	0.125N	0.085N	0.158N	0.018N*
	RTE P-Value	0.042N*	0.204N	0.094N	0.074N	0.190N	0.026N*
Lung * Infiltration Cellular,Histiocyte	Simple Incidence	8/38 (21.1%)	3/32 (9.4%)	8/34 (23.5%)	12/39 (30.8%)	10/44 (22.7%)	13/42 (31.0%)
	Poly-K Incidence	8/24.4 (32.8%)	3/17.2 (17.4%)	8/19.0 (42.0%)	12/26.3 (45.6%)	10/27.3 (36.6%)	13/30.3 (42.9%)
	Terminal Incidence	3/4 (75.0%)	1/3 (33.3%)	2/2 (100.0%)	2/3 (66.7%)	0/4 (0.0%)	3/4 (75.0%)
	Time-to-First	488	651	468	556	434	525
	Poly-K P-Value	0.116	0.218N	0.371	0.245	0.503	0.305
	Severity Profile	1 5 2 0	2 0 0 1	2 3 2 1	6 5 1 0	5 2 3 0	3 3 6 1
	JT/SW P-Value	0.052	0.916	0.459	0.275	0.447	0.169
	RTE P-Value	0.042 *	0.112N	0.395	0.226	0.479	0.124
Urinary System							
Kidney * Casts Protein	Simple Incidence	8/50 (16.0%)	4/48 (8.3%)	3/46 (6.5%)	5/49 (10.2%)	6/50 (12.0%)	6/46 (13.0%)
	Poly-K Incidence	8/35.9 (22.3%)	4/34.0 (11.8%)	3/29.6 (10.1%)	5/34.2 (14.6%)	6/31.2 (19.2%)	6/33.4 (17.9%)
	Terminal Incidence	5/16 (31.3%)	2/19 (10.5%)	0/14 (0.0%)	2/13 (15.4%)	3/10 (30.0%)	2/8 (25.0%)
	Time-to-First	450	524	434	261	434	485
	Poly-K P-Value	0.528	0.194N	0.160N	0.299N	0.497N	0.439N
	Severity Profile	8 0 0 0	3 1 0 0	3 0 0 0	4 1 0 0	5 1 0 0	2 4 0 0
	JT/SW P-Value	0.467	0.864	0.955	0.910	0.856	0.770
	RTE P-Value	0.449	0.139N	0.083N	0.212N	0.280N	0.383N
Kidney * Cyst,Cortex	Simple Incidence	5/50 (10.0%)	8/48 (16.7%)	5/46 (10.9%)	7/49 (14.3%)	10/50 (20.0%)	9/46 (19.6%)
	Poly-K Incidence	5/36.2 (13.8%)	8/34.8 (23.0%)	5/30.2 (16.6%)	7/33.9 (20.7%)	10/33.7 (29.7%)	9/33.0 (27.3%)
	Terminal Incidence	1/16 (6.3%)	5/19 (26.3%)	1/14 (7.1%)	4/13 (30.8%)	2/10 (20.0%)	3/8 (37.5%)
	Time-to-First	488	497	505	513	289	493
	Poly-K P-Value	0.064	0.242	0.514	0.327	0.087	0.133
Kidney * Cyst,Renal Tubule	Simple Incidence	9/50 (18.0%)	8/48 (16.7%)	12/46 (26.1%)	15/49 (30.6%)	12/50 (24.0%)	6/46 (13.0%)
	Poly-K Incidence	9/36.2 (24.8%)	8/34.3 (23.3%)	12/32.1 (37.4%)	15/36.1 (41.6%)	12/33.9 (35.4%)	6/33.4 (18.0%)
	Terminal Incidence	5/16 (31.3%)	4/19 (21.1%)	5/14 (35.7%)	9/13 (69.2%)	1/10 (10.0%)	0/8 (0.0%)
	Time-to-First	446	534	138	261	434	485
	Poly-K P-Value	0.462	0.551N	0.187	0.093	0.235	0.340N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 9. Nonneoplasms by Body System for Terminal Sacrifice Females Bisphenol-A Continuous Dose Arm								
System and Nonneoplasm		Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000	
Kidney * Hyperplasia, Transitional Epithelium	Simple Incidence	12/50 (24.0%)	9/48 (18.8%)	7/46 (15.2%)	8/49 (16.3%)	9/50 (18.0%)	9/46 (19.6%)	
	Poly-K Incidence	12/35.4 (33.9%)	9/33.8 (26.6%)	7/30.0 (23.3%)	8/34.2 (23.4%)	9/30.9 (29.1%)	9/32.7 (27.5%)	
	Terminal Incidence	7/16 (43.8%)	7/19 (36.8%)	2/14 (14.3%)	4/13 (30.8%)	3/10 (30.0%)	2/8 (25.0%)	
	Time-to-First	569	534	541	542	562	510	
	Poly-K P-Value	0.345N	0.342N	0.246N	0.233N	0.438N	0.374N	
	Severity Profile	8 4 0 0	8 1 0 0	5 2 0 0	6 1 1 0	8 1 0 0	6 2 0 1	
	JT/SW P-Value	0.300N	0.228N	0.158N	0.180N	0.204N	0.256N	
	RTE P-Value	0.314N	0.223N	0.132N	0.153N	0.192N	0.293N	
Kidney * Mineralization	Simple Incidence	30/50 (60.0%)	23/48 (47.9%)	25/46 (54.3%)	25/49 (51.0%)	24/50 (48.0%)	26/46 (56.5%)	
	Poly-K Incidence	30/42.9 (69.9%)	23/37.8 (60.9%)	25/40.3 (62.0%)	25/40.6 (61.6%)	24/39.3 (61.0%)	26/38.6 (67.4%)	
	Terminal Incidence	10/16 (62.5%)	12/19 (63.2%)	4/14 (28.6%)	7/13 (53.8%)	3/10 (30.0%)	6/8 (75.0%)	
	Time-to-First	446	505	138	377	289	493	
	Poly-K P-Value	0.409N	0.256N	0.286N	0.270N	0.253N	0.497N	
	Severity Profile	21 8 1 0	20 3 0 0	18 7 0 0	18 7 0 0	17 5 2 0	16 7 2 1	
	JT/SW P-Value	0.475	0.945	0.814	0.888	0.925	0.663	
	RTE P-Value	0.446	0.059N	0.274N	0.173N	0.135N	0.487N	
Kidney * Nephropathy	Simple Incidence	19/50 (38.0%)	28/48 (58.3%)	21/46 (45.7%)	21/49 (42.9%)	21/50 (42.0%)	25/46 (54.3%)	
	Poly-K Incidence	19/39.9 (47.6%)	28/40.6 (69.0%)	21/34.4 (61.0%)	21/38.5 (54.5%)	21/35.5 (59.2%)	25/38.2 (65.4%)	
	Terminal Incidence	6/16 (37.5%)	12/19 (63.2%)	7/14 (50.0%)	7/13 (53.8%)	5/10 (50.0%)	4/8 (50.0%)	
	Time-to-First	488	84	505	513	489	43	
	Poly-K P-Value	0.207	0.033 *	0.164	0.344	0.206	0.073	
	Severity Profile	18 0 1 0	16 9 0 3	17 2 1 1	12 5 2 2	12 4 3 2	18 3 1 3	
	JT/SW P-Value	0.186	0.004 ** ¹	0.039 * ¹	0.071	0.100	0.034 *	
	RTE P-Value	0.188	0.005 **	0.183	0.135	0.142	0.027 *	

P-values for dose trend are presented in the "Control" column.

N indicates a negative trend or negative treatment comparison to control with corresponding lower-tail p-values.

¹ Nonsignificant SW test due to the assumption of monotonicity.

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 10. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Alimentary System							
Liver * Angiectasis	Simple Incidence	1/50 (2.0%)	8/47 (17.0%)	4/48 (8.3%)	4/50 (8.0%)	3/50 (6.0%)	2/45 (4.4%)
	Poly-K Incidence	1/33.7 (3.0%)	8/35.1 (22.8%)	4/33.4 (12.0%)	4/34.0 (11.8%)	3/33.6 (8.9%)	2/28.5 (7.0%)
	Terminal Incidence	1/15 (6.7%)	4/16 (25.0%)	2/17 (11.8%)	3/14 (21.4%)	3/16 (18.8%)	1/11 (9.1%)
	Time-to-First	727 (T)	619	509	573	725 (T)	711
	Poly-K P-Value	0.332N	0.016 *	0.172	0.177	0.301	0.441
	Severity Profile	0 1 0 0	3 4 1 0	1 3 0 0	1 3 0 0	0 3 0 0	0 1 1 0
	JT/SW P-Value	0.295N	0.994N	0.922N	0.936N	0.891N	0.830N
	RTE P-Value	0.268N	0.004 **	0.138	0.142	0.222	0.316
Liver * Basophilic Focus	Simple Incidence	5/50 (10.0%)	5/47 (10.6%)	6/48 (12.5%)	8/50 (16.0%)	3/50 (6.0%)	4/45 (8.9%)
	Poly-K Incidence	5/34.3 (14.6%)	5/34.8 (14.4%)	6/34.4 (17.4%)	8/34.2 (23.4%)	3/33.6 (8.9%)	4/29.3 (13.6%)
	Terminal Incidence	3/15 (20.0%)	3/16 (18.8%)	1/17 (5.9%)	5/14 (35.7%)	3/16 (18.8%)	2/11 (18.2%)
	Time-to-First	622	553	476	600	725 (T)	509
	Poly-K P-Value	0.427N	0.624N	0.503	0.263	0.365N	0.600N
Liver * Clear Cell Focus	Simple Incidence	11/50 (22.0%)	7/47 (14.9%)	11/48 (22.9%)	14/50 (28.0%)	10/50 (20.0%)	8/45 (17.8%)
	Poly-K Incidence	11/35.7 (30.8%)	7/34.5 (20.3%)	11/34.4 (32.0%)	14/36.5 (38.4%)	10/34.9 (28.7%)	8/30.0 (26.7%)
	Terminal Incidence	6/15 (40.0%)	5/16 (31.3%)	7/17 (41.2%)	6/14 (42.9%)	7/16 (43.8%)	5/11 (45.5%)
	Time-to-First	566	615	532	485	540	501
	Poly-K P-Value	0.421	0.226N	0.561	0.329	0.526N	0.463N
Liver * Degeneration,Cystic	Simple Incidence	21/50 (42.0%)	19/47 (40.4%)	19/48 (39.6%)	22/50 (44.0%)	18/50 (36.0%)	18/45 (40.0%)
	Poly-K Incidence	21/38.2 (55.0%)	19/37.8 (50.3%)	19/35.9 (52.9%)	22/36.8 (59.7%)	18/37.6 (47.9%)	18/32.6 (55.2%)
	Terminal Incidence	9/15 (60.0%)	8/16 (50.0%)	9/17 (52.9%)	10/14 (71.4%)	7/16 (43.8%)	9/11 (81.8%)
	Time-to-First	425	516	532	574	411	386
	Poly-K P-Value	0.516N	0.426N	0.523N	0.421	0.342N	0.592
	Severity Profile	14 6 1 0	11 8 0 0	13 5 0 1	12 10 0 0	9 7 2 0	14 3 1 0
	JT/SW P-Value	0.377N	0.484N	0.472N	0.631N	0.494N	0.486N
	RTE P-Value	0.372N	0.482N	0.401N	0.358	0.375N	0.365N
Liver * Fatty Change	Simple Incidence	4/50 (8.0%)	8/47 (17.0%)	5/48 (10.4%)	5/50 (10.0%)	4/50 (8.0%)	2/45 (4.4%)
	Poly-K Incidence	4/35.1 (11.4%)	8/36.5 (21.9%)	5/33.2 (15.1%)	5/35.4 (14.1%)	4/34.4 (11.6%)	2/29.1 (6.9%)
	Terminal Incidence	2/15 (13.3%)	0/16 (0.0%)	1/17 (5.9%)	1/14 (7.1%)	1/16 (6.3%)	1/11 (9.1%)
	Time-to-First	225	595	588	342	631	509
	Poly-K P-Value	0.160N	0.188	0.465	0.506	0.636	0.425N
	Severity Profile	0 1 1 2	1 3 1 3	2 1 1 1	0 4 0 1	0 3 1 0	0 1 0 1
	JT/SW P-Value	0.104N	0.901N	0.700N	0.721N	0.605N	0.365N
	RTE P-Value	0.095N	0.074	0.374	0.392	0.473N	0.270N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 10. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Continuous Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Liver * Fibrosis,Biliary Tract	Simple Incidence	13/50 (26.0%)	19/47 (40.4%)	19/48 (39.6%)	15/50 (30.0%)	19/50 (38.0%)	10/45 (22.2%)
	Poly-K Incidence	13/35.9 (36.2%)	19/36.8 (51.6%)	19/36.8 (51.7%)	15/36.5 (41.1%)	19/37.5 (50.7%)	10/31.1 (32.1%)
	Terminal Incidence	7/15 (46.7%)	8/16 (50.0%)	10/17 (58.8%)	5/14 (35.7%)	6/16 (37.5%)	3/11 (27.3%)
	Time-to-First	566	613	476	573	526	463
	Poly-K P-Value	0.370N	0.127	0.125	0.422	0.143	0.462N
	Severity Profile	9 4 0 0	13 6 0 0	12 6 1 0	10 5 0 0	11 5 3 0	7 3 0 0
	JT/SW P-Value	0.342N	0.931N	0.967N	0.789N	0.927N	0.470N
	RTE P-Value	0.300N	0.068	0.069	0.331	0.075	0.351N
Liver * Hepatodiaphragmatic Nodule	Simple Incidence	6/50 (12.0%)	2/47 (4.3%)	4/48 (8.3%)	3/50 (6.0%)	7/50 (14.0%)	5/45 (11.1%)
	Poly-K Incidence	6/34.6 (17.3%)	2/34.2 (5.9%)	4/32.8 (12.2%)	3/34.6 (8.7%)	7/35.4 (19.7%)	5/30.9 (16.2%)
	Terminal Incidence	3/15 (20.0%)	1/16 (6.3%)	3/17 (17.6%)	1/14 (7.1%)	2/16 (12.5%)	1/11 (9.1%)
	Time-to-First	603	683	579	244	540	462
	Poly-K P-Value	0.267	0.131N	0.402N	0.236N	0.519	0.584N
Liver * Hyperplasia,Bile Duct	Simple Incidence	16/50 (32.0%)	19/47 (40.4%)	17/48 (35.4%)	16/50 (32.0%)	16/50 (32.0%)	12/45 (26.7%)
	Poly-K Incidence	16/38.5 (41.5%)	19/38.3 (49.5%)	17/37.0 (45.9%)	16/37.3 (42.9%)	16/36.1 (44.3%)	12/31.6 (37.9%)
	Terminal Incidence	6/15 (40.0%)	6/16 (37.5%)	7/17 (41.2%)	5/14 (35.7%)	7/16 (43.8%)	5/11 (45.5%)
	Time-to-First	284	452	532	368	541	383
	Poly-K P-Value	0.325N	0.310	0.437	0.546	0.497	0.475N
	Severity Profile	7 8 1 0	6 9 2 2	9 3 4 1	8 5 3 0	6 5 3 2	6 4 2 0
	JT/SW P-Value	0.185N	0.864N	0.744N	0.625N	0.689N	0.407N
	RTE P-Value	0.174N	0.133	0.342	0.494	0.412	0.303N
Liver * Hyperplasia,Oval Cell	Simple Incidence	4/50 (8.0%)	1/47 (2.1%)	0/48 (0.0%)	1/50 (2.0%)	3/50 (6.0%)	2/45 (4.4%)
	Poly-K Incidence	4/34.0 (11.8%)	1/34.0 (2.9%)	0/32.3 (0.0%)	1/33.9 (3.0%)	3/33.8 (8.9%)	2/29.0 (6.9%)
	Terminal Incidence	2/15 (13.3%)	1/16 (6.3%)	0/17 (0.0%)	0/14 (0.0%)	2/16 (12.5%)	0/11 (0.0%)
	Time-to-First	647	723 (T)	----	617	668	637
	Poly-K P-Value	0.480N	0.175N	0.065N	0.176N	0.504N	0.412N
	Severity Profile	3 1 0 0	1 0 0 0	---	1 0 0 0	1 1 0 1	1 1 0 0
	JT/SW P-Value	0.424N	0.095N	0.017N* ¹	0.026N* ¹	0.098N	0.133N
	RTE P-Value	0.439N	0.080N	0.027N*	0.070N	0.312N	0.238N
Liver * Infiltration Cellular,Mononuclear Cell	Simple Incidence	35/50 (70.0%)	29/47 (61.7%)	37/48 (77.1%)	36/50 (72.0%)	34/50 (68.0%)	28/45 (62.2%)
	Poly-K Incidence	35/42.3 (82.6%)	29/40.1 (72.3%)	37/42.6 (86.9%)	36/42.3 (85.1%)	34/40.5 (84.0%)	28/35.4 (79.0%)
	Terminal Incidence	14/15 (93.3%)	13/16 (81.3%)	16/17 (94.1%)	13/14 (92.9%)	15/16 (93.8%)	11/11 (100.0%)
	Time-to-First	284	418	393	244	443	383
	Poly-K P-Value	0.366	0.169N	0.387	0.496	0.560	0.446N
	Severity Profile	21 14 0 0	16 13 0 0	22 15 0 0	26 10 0 0	21 13 0 0	19 9 0 0
	JT/SW P-Value	0.192N	0.288N	0.609N	0.444N	0.488N	0.208N
	RTE P-Value	0.192N	0.280N	0.247	0.356N	0.396N	0.158N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 10. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Continuous Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Liver * Necrosis,Hepatocyte	Simple Incidence	2/50 (4.0%)	3/47 (6.4%)	1/48 (2.1%)	1/50 (2.0%)	4/50 (8.0%)	1/45 (2.2%)
	Poly-K Incidence	2/34.5 (5.8%)	3/34.5 (8.7%)	1/32.5 (3.1%)	1/34.5 (2.9%)	4/35.6 (11.2%)	1/28.7 (3.5%)
	Terminal Incidence	0/15 (0.0%)	2/16 (12.5%)	0/17 (0.0%)	0/14 (0.0%)	0/16 (0.0%)	0/11 (0.0%)
	Time-to-First	543	585	678	244	381	656
	Poly-K P-Value	0.528N	0.500	0.521N	0.500N	0.350	0.564N
	Severity Profile	0 1 0 1	2 1 0 0	0 0 0 1	1 0 0 0	1 0 1 2	0 0 0 1
	JT/SW P-Value	0.464N	0.685N	0.379N	0.366N	0.640N	0.449N
	RTE P-Value	0.441N	0.293	0.319N	0.301N	0.161	0.334N
Liver * Tension Lipidosis	Simple Incidence	3/50 (6.0%)	2/47 (4.3%)	3/48 (6.3%)	1/50 (2.0%)	2/50 (4.0%)	7/45 (15.6%)
	Poly-K Incidence	3/33.8 (8.9%)	2/35.5 (5.6%)	3/33.7 (8.9%)	1/33.5 (3.0%)	2/33.9 (5.9%)	7/30.8 (22.7%)
	Terminal Incidence	1/15 (6.7%)	0/16 (0.0%)	0/17 (0.0%)	1/14 (7.1%)	1/16 (6.3%)	4/11 (36.4%)
	Time-to-First	709	452	547	727 (T)	637	330
	Poly-K P-Value	0.081	0.478N	0.664	0.307N	0.499N	0.111
	Severity Profile	0 0 1 2	0 2 0 0	0 2 0 1	0 1 0 0	0 1 0 1	0 4 1 2
	JT/SW P-Value	0.093	0.671	0.578	0.806	0.826	0.038 *
	RTE P-Value	0.076	0.337N	0.498	0.149N	0.326N	0.025 *
Liver * Vacuolization Cytoplasmic	Simple Incidence	12/50 (24.0%)	8/47 (17.0%)	11/48 (22.9%)	15/50 (30.0%)	14/50 (28.0%)	14/45 (31.1%)
	Poly-K Incidence	12/37.3 (32.2%)	8/35.7 (22.4%)	11/34.7 (31.7%)	15/38.9 (38.6%)	14/37.8 (37.1%)	14/32.2 (43.5%)
	Terminal Incidence	4/15 (26.7%)	4/16 (25.0%)	4/17 (23.5%)	5/14 (35.7%)	6/16 (37.5%)	7/11 (63.6%)
	Time-to-First	520	489	572	368	411	330
	Poly-K P-Value	0.057	0.245N	0.583N	0.364	0.418	0.227
	Severity Profile	6 3 3 0	2 3 3 0	3 4 4 0	6 7 2 0	4 6 2 2	2 8 2 2
	JT/SW P-Value	0.059	0.763	0.580	0.317	0.345	0.204
	RTE P-Value	0.062	0.269N	0.484	0.259	0.272	0.155
Pancreas * Basophilic Focus	Simple Incidence	2/50 (4.0%)	2/46 (4.3%)	2/48 (4.2%)	1/49 (2.0%)	4/48 (8.3%)	4/44 (9.1%)
	Poly-K Incidence	2/33.7 (5.9%)	2/33.4 (6.0%)	2/33.0 (6.1%)	1/33.3 (3.0%)	4/33.6 (11.9%)	4/30.2 (13.2%)
	Terminal Incidence	2/15 (13.3%)	1/16 (6.3%)	1/17 (5.9%)	0/14 (0.0%)	2/16 (12.5%)	1/11 (9.1%)
	Time-to-First	727 (T)	692	484	588	465	372
	Poly-K P-Value	0.113	0.692	0.688	0.504N	0.332	0.283
Pancreas * Degeneration,Acinus	Simple Incidence	42/50 (84.0%)	36/46 (78.3%)	43/48 (89.6%)	43/49 (87.8%)	44/48 (91.7%)	37/44 (84.1%)
	Poly-K Incidence	42/46.5 (90.2%)	36/41.2 (87.4%)	43/46.0 (93.5%)	43/46.0 (93.5%)	44/45.9 (95.8%)	37/42.0 (88.0%)
	Terminal Incidence	14/15 (93.3%)	16/16 (100.0%)	15/17 (88.2%)	13/14 (92.9%)	16/16 (100.0%)	10/11 (90.9%)
	Time-to-First	225	176	284	244	348	311
	Poly-K P-Value	0.349	0.460N	0.417	0.412	0.234	0.502N
	Severity Profile	7 9 13 13	6 10 13 7	9 18 12 4	6 24 6 7	3 13 16 12	7 12 8 10
	JT/SW P-Value	0.297	0.862	0.943	0.961	0.196	0.559
	RTE P-Value	0.312	0.128N	0.082N	0.084N	0.144	0.241N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 10. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Pancreas * Infiltration Cellular,Lymphocyte	Simple Incidence	36/50 (72.0%)	32/46 (69.6%)	43/48 (89.6%)	38/49 (77.6%)	38/48 (79.2%)	36/44 (81.8%)
	Poly-K Incidence	36/42.7 (84.4%)	32/39.7 (80.7%)	43/46.0 (93.5%)	38/43.8 (86.8%)	38/42.4 (89.6%)	36/41.3 (87.1%)
	Terminal Incidence	13/15 (86.7%)	15/16 (93.8%)	15/17 (88.2%)	12/14 (85.7%)	16/16 (100.0%)	9/11 (81.8%)
	Time-to-First	284	418	284	244	381	330
	Poly-K P-Value	0.233	0.430N	0.119	0.495	0.320	0.483
	Severity Profile	10 17 9 0	12 16 4 0	23 16 4 0	15 16 7 0	9 25 4 0	16 16 4 0
	JT/SW P-Value	0.320	0.825	0.645	0.688	0.452	0.621
	RTE P-Value	0.327	0.157N	0.411N	0.417N	0.339	0.376N
Pancreas * Lipomatosis	Simple Incidence	7/50 (14.0%)	7/46 (15.2%)	12/48 (25.0%)	11/49 (22.4%)	11/48 (22.9%)	9/44 (20.5%)
	Poly-K Incidence	7/34.4 (20.3%)	7/35.2 (19.9%)	12/34.3 (35.0%)	11/35.9 (30.6%)	11/35.0 (31.5%)	9/30.6 (29.4%)
	Terminal Incidence	5/15 (33.3%)	1/16 (6.3%)	6/17 (35.3%)	3/14 (21.4%)	6/16 (37.5%)	3/11 (27.3%)
	Time-to-First	526	489	576	490	513	501
	Poly-K P-Value	0.117	0.601N	0.130	0.232	0.211	0.283
	Severity Profile	0 1 3 3	0 3 3 1	0 0 5 7	0 4 5 2	0 5 2 4	0 3 3 3
	JT/SW P-Value	0.161	0.481	0.074	0.142	0.170	0.211
	RTE P-Value	0.166	0.497	0.071	0.186	0.160	0.242
Pancreas * Pigmentation	Simple Incidence	29/50 (58.0%)	19/46 (41.3%)	26/48 (54.2%)	26/49 (53.1%)	30/48 (62.5%)	26/44 (59.1%)
	Poly-K Incidence	29/45.0 (64.4%)	19/37.6 (50.5%)	26/42.0 (61.9%)	26/43.4 (59.9%)	30/42.4 (70.8%)	26/39.6 (65.6%)
	Terminal Incidence	8/15 (53.3%)	10/16 (62.5%)	7/17 (41.2%)	5/14 (35.7%)	11/16 (68.8%)	7/11 (63.6%)
	Time-to-First	72	418	393	244	348	311
	Poly-K P-Value	0.180	0.136N	0.490N	0.410N	0.336	0.548
	Severity Profile	16 13 0 0	11 7 1 0	22 4 0 0	17 9 0 0	20 9 1 0	15 11 0 0
	JT/SW P-Value	0.174	0.938	0.929	0.878	0.582	0.615
	RTE P-Value	0.170	0.051N	0.121N	0.226N	0.454	0.488
Cardiovascular System							
Heart * Cardiomyopathy	Simple Incidence	44/50 (88.0%)	44/48 (91.7%)	43/48 (89.6%)	45/50 (90.0%)	44/50 (88.0%)	41/46 (89.1%)
	Poly-K Incidence	44/46.0 (95.6%)	44/45.0 (97.7%)	43/45.6 (94.2%)	45/46.1 (97.6%)	44/45.8 (96.0%)	41/43.1 (95.2%)
	Terminal Incidence	15/15 (100.0%)	16/16 (100.0%)	16/17 (94.1%)	14/14 (100.0%)	16/16 (100.0%)	11/11 (100.0%)
	Time-to-First	225	292	284	342	411	304
	Poly-K P-Value	0.475N	0.506	0.581N	0.521	0.708	0.705N
	Severity Profile	12 21 10 1	11 22 10 1	13 17 10 3	12 21 8 4	14 22 6 2	14 16 6 5
	JT/SW P-Value	0.318N	0.675N	0.719N	0.769N	0.394N	0.526N
	RTE P-Value	0.320N	0.326	0.378	0.340	0.304N	0.499N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 10. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Endocrine System							
Adrenal Cortex * Angiectasis	Simple Incidence	2/50 (4.0%)	0/48 (0.0%)	4/48 (8.3%)	1/50 (2.0%)	1/48 (2.1%)	2/45 (4.4%)
	Poly-K Incidence	2/34.5 (5.8%)	0/34.0 (0.0%)	4/33.4 (12.0%)	1/33.5 (3.0%)	1/33.2 (3.0%)	2/28.4 (7.0%)
	Terminal Incidence	0/15 (0.0%)	0/16 (0.0%)	1/17 (5.9%)	1/14 (7.1%)	0/16 (0.0%)	1/11 (9.1%)
	Time-to-First	494	---	576	726 (T)	581	671
	Poly-K P-Value	0.480	0.239N	0.319	0.510N	0.514N	0.625
	Severity Profile	0 0 1 1	---	0 3 0 1	0 1 0 0	0 1 0 0	0 1 0 1
	JT/SW P-Value	0.480	0.918	0.178	0.497	0.635	0.600
	RTE P-Value	0.467	0.094N	0.124	0.283N	0.293N	0.458
Adrenal Cortex * Degeneration,Cystic	Simple Incidence	4/50 (8.0%)	6/48 (12.5%)	2/48 (4.2%)	2/50 (4.0%)	2/48 (4.2%)	3/45 (6.7%)
	Poly-K Incidence	4/33.8 (11.8%)	6/35.1 (17.1%)	2/32.7 (6.1%)	2/33.5 (6.0%)	2/33.2 (6.0%)	3/29.0 (10.4%)
	Terminal Incidence	2/15 (13.3%)	0/16 (0.0%)	1/17 (5.9%)	2/14 (14.3%)	0/16 (0.0%)	1/11 (9.1%)
	Time-to-First	709	619	617	727 (T)	630	501
	Poly-K P-Value	0.161N	0.390	0.350N	0.338N	0.343N	0.586N
	Severity Profile	0 3 0 1	3 3 0 0	0 0 1 1	2 0 0 0	0 2 0 0	1 0 0 2
	JT/SW P-Value	0.141N	0.735N	0.301N	0.255N	0.270N	0.344N
	RTE P-Value	0.152N	0.207	0.227N	0.160N	0.196N	0.398N
Adrenal Cortex * Hyperplasia	Simple Incidence	6/50 (12.0%)	9/48 (18.8%)	8/48 (16.7%)	7/50 (14.0%)	6/48 (12.5%)	7/45 (15.6%)
	Poly-K Incidence	6/35.3 (17.0%)	9/35.3 (25.5%)	8/32.7 (24.5%)	7/34.4 (20.4%)	6/33.6 (17.8%)	7/30.5 (23.0%)
	Terminal Incidence	1/15 (6.7%)	4/16 (25.0%)	6/17 (35.3%)	3/14 (21.4%)	4/16 (25.0%)	1/11 (9.1%)
	Time-to-First	559	539	666	608	479	534
	Poly-K P-Value	0.509	0.278	0.321	0.479	0.590	0.382
	Severity Profile	3 2 1 0	5 4 0 0	5 2 1 0	3 3 1 0	3 3 0 0	4 3 0 0
	JT/SW P-Value	0.464N	0.811N	0.807N	0.739N	0.658N	0.748N
	RTE P-Value	0.461N	0.189	0.274	0.383	0.480	0.330
Adrenal Cortex * Hypertrophy	Simple Incidence	2/50 (4.0%)	0/48 (0.0%)	1/48 (2.1%)	1/50 (2.0%)	2/48 (4.2%)	4/45 (8.9%)
	Poly-K Incidence	2/34.2 (5.8%)	0/34.0 (0.0%)	1/32.8 (3.1%)	1/33.6 (3.0%)	2/33.2 (6.0%)	4/29.0 (13.8%)
	Terminal Incidence	1/15 (6.7%)	0/16 (0.0%)	0/17 (0.0%)	0/14 (0.0%)	1/16 (6.3%)	2/11 (18.2%)
	Time-to-First	566	---	579	697	585	596
	Poly-K P-Value	0.062	0.237N	0.516N	0.506N	0.685	0.259
	Severity Profile	1 1 0 0	---	0 0 0 1	1 0 0 0	1 1 0 0	2 2 0 0
	JT/SW P-Value	0.058	0.918	0.823	0.863	0.613	0.129
	RTE P-Value	0.046 *	0.110N	0.309N	0.290N	0.482	0.071

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 10. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Continuous Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Adrenal Cortex * Vacuolization Cytoplasmic	Simple Incidence	18/50 (36.0%)	12/48 (25.0%)	22/48 (45.8%)	14/50 (28.0%)	21/48 (43.8%)	15/45 (33.3%)
	Poly-K Incidence	18/39.6 (45.5%)	12/36.9 (32.5%)	22/37.2 (59.1%)	14/36.0 (38.9%)	21/38.3 (54.8%)	15/32.7 (45.9%)
	Terminal Incidence	5/15 (33.3%)	5/16 (31.3%)	11/17 (64.7%)	5/14 (35.7%)	9/16 (56.3%)	6/11 (54.5%)
	Time-to-First	486	418	476	485	411	330
	Poly-K P-Value	0.224	0.169N	0.154	0.361N	0.268	0.584
	Severity Profile	7 8 3 0	5 5 2 0	7 14 1 0	2 10 2 0	3 15 2 1	2 9 1 3
	JT/SW P-Value	0.171	0.880	0.199	0.547	0.184	0.372
	RTE P-Value	0.175	0.138N	0.171	0.277N	0.135	0.454
Adrenal Medulla * Hyperplasia	Simple Incidence	5/50 (10.0%)	3/48 (6.3%)	7/47 (14.9%)	6/50 (12.0%)	8/50 (16.0%)	5/45 (11.1%)
	Poly-K Incidence	5/35.1 (14.2%)	3/34.5 (8.7%)	7/33.5 (20.9%)	6/34.5 (17.4%)	8/34.4 (23.3%)	5/30.1 (16.6%)
	Terminal Incidence	1/15 (6.7%)	1/16 (6.3%)	3/17 (17.6%)	3/14 (21.4%)	5/16 (31.3%)	0/11 (0.0%)
	Time-to-First	578	650	568	574	581	534
	Poly-K P-Value	0.166	0.363N	0.341	0.487	0.253	0.533
	Severity Profile	3 2 0 0	1 0 2 0	4 1 1 1	4 1 0 1	3 5 0 0	2 3 0 0
	JT/SW P-Value	0.196	0.730	0.248	0.366	0.222	0.376
	RTE P-Value	0.207	0.308N	0.220	0.378	0.164	0.422
Parathyroid Gland * Hyperplasia	Simple Incidence	11/49 (22.4%)	11/46 (23.9%)	23/47 (48.9%)	18/50 (36.0%)	18/50 (36.0%)	12/46 (26.1%)
	Poly-K Incidence	11/36.7 (30.0%)	11/33.9 (32.4%)	23/37.5 (61.3%)	18/38.4 (46.9%)	18/39.0 (46.2%)	12/32.3 (37.2%)
	Terminal Incidence	3/15 (20.0%)	6/16 (37.5%)	10/17 (58.8%)	5/14 (35.7%)	5/16 (31.3%)	2/11 (18.2%)
	Time-to-First	543	650	476	485	443	534
	Poly-K P-Value	0.166	0.514	0.004 **	0.095	0.105	0.351
	Severity Profile	3 7 0 1	7 3 0 1	1 13 6 3	2 9 3 4	9 5 2 2	4 5 3 0
	JT/SW P-Value	0.230	0.514	<.001 *** ¹	0.008 ** ¹	0.025 * ¹	0.066
	RTE P-Value	0.227	0.474N	<.001 ***	0.039 *	0.101	0.349
Pituitary Gland * Angiectasis	Simple Incidence	6/48 (12.5%)	11/48 (22.9%)	10/48 (20.8%)	8/50 (16.0%)	9/50 (18.0%)	6/45 (13.3%)
	Poly-K Incidence	6/33.5 (17.9%)	11/36.8 (29.9%)	10/35.7 (28.0%)	8/34.8 (23.0%)	9/35.3 (25.5%)	6/29.1 (20.6%)
	Terminal Incidence	1/14 (7.1%)	3/16 (18.8%)	4/17 (23.5%)	5/14 (35.7%)	4/16 (25.0%)	4/11 (36.4%)
	Time-to-First	494	516	412	582	566	501
	Poly-K P-Value	0.491N	0.182	0.235	0.412	0.317	0.521
	Severity Profile	0 0 0 6	0 1 0 10	0 0 0 10	0 0 2 6	0 0 1 8	0 1 0 5
	JT/SW P-Value	0.352N	0.902N	0.915N	0.765N	0.833N	0.673N
	RTE P-Value	0.347N	0.104	0.147	0.354	0.247	0.478
Pituitary Gland * Cyst Multilocular, Pars Distalis	Simple Incidence	2/48 (4.2%)	0/48 (0.0%)	0/48 (0.0%)	3/50 (6.0%)	4/50 (8.0%)	5/45 (11.1%)
	Poly-K Incidence	2/32.3 (6.2%)	0/34.0 (0.0%)	0/32.3 (0.0%)	3/34.0 (8.8%)	4/34.7 (11.5%)	5/30.0 (16.7%)
	Terminal Incidence	2/14 (14.3%)	0/16 (0.0%)	0/17 (0.0%)	1/14 (7.1%)	2/16 (12.5%)	1/11 (9.1%)
	Time-to-First	726 (T)	----	----	609	526	464
	Poly-K P-Value	0.007 **	0.224N	0.236N	0.525	0.369	0.180

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 10. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Pituitary Gland * Cyst,Pars Distalis	Simple Incidence	8/48 (16.7%)	4/48 (8.3%)	5/48 (10.4%)	6/50 (12.0%)	5/50 (10.0%)	2/45 (4.4%)
	Poly-K Incidence	8/34.9 (22.9%)	4/35.3 (11.3%)	5/34.0 (14.7%)	6/35.3 (17.0%)	5/34.6 (14.5%)	2/29.1 (6.9%)
	Terminal Incidence	1/14 (7.1%)	0/16 (0.0%)	2/17 (11.8%)	3/14 (21.4%)	3/16 (18.8%)	1/11 (9.1%)
	Time-to-First	284	595	509	244	581	330
	Poly-K P-Value	0.117N	0.162N	0.283N	0.372N	0.273N	0.074N
Pituitary Gland * Hyperplasia,Pars Distalis	Simple Incidence	11/48 (22.9%)	9/48 (18.8%)	19/48 (39.6%)	15/50 (30.0%)	17/50 (34.0%)	19/45 (42.2%)
	Poly-K Incidence	11/36.2 (30.4%)	9/36.3 (24.8%)	19/37.8 (50.3%)	15/37.8 (39.7%)	17/38.5 (44.1%)	19/34.2 (55.6%)
	Terminal Incidence	4/14 (28.6%)	4/16 (25.0%)	9/17 (52.9%)	4/14 (28.6%)	7/16 (43.8%)	6/11 (54.5%)
	Time-to-First	467	489	284	368	443	372
	Poly-K P-Value	0.005 **	0.393N	0.057	0.270	0.153	0.022 *
	Severity Profile	3 4 4 0	0 4 4 1	5 8 2 4	4 6 3 2	4 7 5 1	3 9 3 4
	JT/SW P-Value	0.011 *	0.624	0.040 * ¹	0.123	0.137	0.021 *
	RTE P-Value	0.010 *	0.415N	0.043 *	0.225	0.119	0.017 *
Pituitary Gland * Hypertrophy,Pars Distalis	Simple Incidence	4/48 (8.3%)	2/48 (4.2%)	3/48 (6.3%)	3/50 (6.0%)	3/50 (6.0%)	1/45 (2.2%)
	Poly-K Incidence	4/33.1 (12.1%)	2/34.6 (5.8%)	3/33.3 (9.0%)	3/34.4 (8.7%)	3/34.1 (8.8%)	1/28.6 (3.5%)
	Terminal Incidence	2/14 (14.3%)	1/16 (6.3%)	1/17 (5.9%)	0/14 (0.0%)	1/16 (6.3%)	0/11 (0.0%)
	Time-to-First	585	539	561	485	637	613
	Poly-K P-Value	0.252N	0.314N	0.497N	0.480N	0.484N	0.221N
	Severity Profile	1 3 0 0	1 0 1 0	2 1 0 0	0 3 0 0	0 3 0 0	0 1 0 0
	JT/SW P-Value	0.196N	0.203N	0.309N	0.356N	0.383N	0.134N
	RTE P-Value	0.196N	0.220N	0.319N	0.315N	0.315N	0.122N
Thyroid Gland * Hyperplasia,C-Cell	Simple Incidence	9/46 (19.6%)	13/40 (32.5%)	15/47 (31.9%)	15/44 (34.1%)	20/44 (45.5%)	11/44 (25.0%)
	Poly-K Incidence	9/34.9 (25.8%)	13/32.8 (39.7%)	15/35.5 (42.3%)	15/34.1 (44.0%)	20/33.8 (59.2%)	11/30.5 (36.0%)
	Terminal Incidence	5/15 (33.3%)	7/16 (43.8%)	7/17 (41.2%)	8/14 (57.1%)	12/16 (75.0%)	5/11 (45.5%)
	Time-to-First	225	585	488	485	513	541
	Poly-K P-Value	0.039 *	0.162	0.105	0.083	0.003 **	0.260
	Severity Profile	5 2 2 0	5 7 1 0	8 4 2 1	8 6 1 0	10 8 2 0	3 7 1 0
	JT/SW P-Value	0.106	0.082	0.102	0.097	0.006 ** ¹	0.068
	RTE P-Value	0.112	0.091	0.099	0.080	0.005 **	0.247
Thyroid Gland * Hyperplasia,Follicular Cell	Simple Incidence	3/46 (6.5%)	2/40 (5.0%)	9/47 (19.1%)	6/44 (13.6%)	3/44 (6.8%)	3/44 (6.8%)
	Poly-K Incidence	3/32.5 (9.2%)	2/31.2 (6.4%)	9/35.1 (25.6%)	6/32.0 (18.8%)	3/31.5 (9.5%)	3/28.6 (10.5%)
	Terminal Incidence	2/15 (13.3%)	0/16 (0.0%)	1/17 (5.9%)	2/14 (14.3%)	0/16 (0.0%)	0/11 (0.0%)
	Time-to-First	720	646	539	342	448	660
	Poly-K P-Value	0.434	0.519N	0.070	0.227	0.651	0.605
	Severity Profile	0 2 1 0	0 1 1 0	0 3 5 1	0 4 2 0	0 1 1 1	0 1 2 0
	JT/SW P-Value	0.493	0.613	0.024 * ¹	0.080	0.182	0.264
	RTE P-Value	0.474	0.413N	0.015 *	0.142	0.461	0.468

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 10. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Thyroid Gland * Ultimobranchial Cyst	Simple Incidence	7/46 (15.2%)	4/40 (10.0%)	6/47 (12.8%)	5/44 (11.4%)	5/44 (11.4%)	3/44 (6.8%)
	Poly-K Incidence	7/34.4 (20.3%)	4/31.4 (12.7%)	6/32.1 (18.7%)	5/32.6 (15.3%)	5/31.7 (15.8%)	3/29.3 (10.2%)
	Terminal Incidence	2/15 (13.3%)	2/16 (12.5%)	4/17 (23.5%)	1/14 (7.1%)	3/16 (18.8%)	0/11 (0.0%)
	Time-to-First	225	619	678	368	513	559
	Poly-K P-Value	0.232N	0.309N	0.556N	0.413N	0.436N	0.221N
Genital System							
Epididymis * Exfoliated Germ Cell	Simple Incidence	10/49 (20.4%)	8/48 (16.7%)	10/48 (20.8%)	12/50 (24.0%)	13/50 (26.0%)	6/46 (13.0%)
	Poly-K Incidence	10/36.5 (27.4%)	8/35.5 (22.6%)	10/35.4 (28.3%)	12/37.4 (32.1%)	13/38.0 (34.2%)	6/30.1 (19.9%)
	Terminal Incidence	3/15 (20.0%)	2/16 (12.5%)	2/17 (11.8%)	3/14 (21.4%)	3/16 (18.8%)	2/11 (18.2%)
	Time-to-First	494	638	539	368	443	501
	Poly-K P-Value	0.429	0.419N	0.572	0.426	0.347	0.335N
	Severity Profile	5 3 1 1	5 1 2 0	1 9 0 0	4 5 2 1	4 7 2 0	4 0 2 0
	JT/SW P-Value	0.489N	0.305N	0.510N	0.649N	0.737N	0.250N
	RTE P-Value	0.468N	0.314N	0.441	0.299	0.228	0.187N
Epididymis * Hypospermia	Simple Incidence	11/49 (22.4%)	11/48 (22.9%)	9/48 (18.8%)	14/50 (28.0%)	11/50 (22.0%)	9/46 (19.6%)
	Poly-K Incidence	11/37.0 (29.7%)	11/36.2 (30.4%)	9/33.6 (26.8%)	14/38.1 (36.7%)	11/37.4 (29.4%)	9/31.4 (28.7%)
	Terminal Incidence	2/15 (13.3%)	5/16 (31.3%)	5/17 (29.4%)	5/14 (35.7%)	3/16 (18.8%)	1/11 (9.1%)
	Time-to-First	225	452	547	342	411	532
	Poly-K P-Value	0.494	0.576	0.497N	0.341	0.592N	0.571N
	Severity Profile	0 0 0 11	0 0 1 10	0 1 0 8	0 0 0 14	0 0 1 10	0 0 1 8
	JT/SW P-Value	0.428N	0.500N	0.367N	0.645N	0.588N	0.464N
	RTE P-Value	0.423N	0.499	0.310N	0.253	0.458N	0.347N
Epididymis * Infiltration Cellular,Lymphocyte	Simple Incidence	10/49 (20.4%)	12/48 (25.0%)	13/48 (27.1%)	15/50 (30.0%)	14/50 (28.0%)	15/46 (32.6%)
	Poly-K Incidence	10/35.5 (28.1%)	12/36.5 (32.9%)	13/34.4 (37.8%)	15/36.2 (41.4%)	14/36.0 (38.9%)	15/34.1 (44.0%)
	Terminal Incidence	4/15 (26.7%)	6/16 (37.5%)	6/17 (35.3%)	9/14 (64.3%)	8/16 (50.0%)	4/11 (36.4%)
	Time-to-First	225	489	576	311	443	386
	Poly-K P-Value	0.067	0.427	0.267	0.166	0.230	0.120
	Severity Profile	8 2 0 0	12 0 0 0	11 2 0 0	13 2 0 0	12 2 0 0	13 2 0 0
	JT/SW P-Value	0.086	0.338	0.273	0.187	0.232	0.131
	RTE P-Value	0.090	0.358	0.240	0.154	0.210	0.101
Epididymis * Polyarteritis	Simple Incidence	0/49 (0.0%)	1/48 (2.1%)	1/48 (2.1%)	1/50 (2.0%)	4/50 (8.0%)	1/46 (2.2%)
	Poly-K Incidence	0/33.7 (0.0%)	1/34.3 (2.9%)	1/32.8 (3.1%)	1/33.9 (3.0%)	4/35.2 (11.4%)	1/29.1 (3.4%)
	Terminal Incidence	0/15 (0.0%)	0/16 (0.0%)	0/17 (0.0%)	0/14 (0.0%)	0/16 (0.0%)	0/11 (0.0%)
	Time-to-First	----	652	576	626	443	534
	Poly-K P-Value	0.063	0.503	0.494	0.501	0.064	0.471
	Severity Profile	---	0 0 1 0	0 1 0 0	1 0 0 0	0 3 1 0	0 0 1 0
	JT/SW P-Value	0.065	0.156	0.228	0.261	0.010 ** 1	0.078
	RTE P-Value	0.083	0.262	0.267	0.276	0.013 * 1	0.255

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 10. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Prostate, Dorsal/Lateral Lobe * Fibrosis	Simple Incidence	9/50 (18.0%)	5/48 (10.4%)	12/48 (25.0%)	9/50 (18.0%)	10/50 (20.0%)	6/46 (13.0%)
	Poly-K Incidence	9/36.6 (24.6%)	5/35.3 (14.2%)	12/35.3 (34.0%)	9/36.3 (24.8%)	10/35.7 (28.0%)	6/30.0 (20.0%)
	Terminal Incidence	3/15 (20.0%)	1/16 (6.3%)	4/17 (23.5%)	2/14 (14.3%)	4/16 (25.0%)	2/11 (18.2%)
	Time-to-First	526	539	284	490	479	509
	Poly-K P-Value	0.417	0.205N	0.263	0.599	0.475	0.440N
	Severity Profile	0 7 0 2	0 2 1 2	3 6 3 0	2 2 1 4	1 8 0 1	0 3 1 2
	JT/SW P-Value	0.485N	0.164N	0.557N	0.608N	0.648N	0.384N
	RTE P-Value	0.476N	0.185N	0.218	0.476	0.431	0.285N
Prostate, Dorsal/Lateral Lobe * Infiltration Cellular,Lymphocyte	Simple Incidence	33/50 (66.0%)	26/48 (54.2%)	27/48 (56.3%)	27/50 (54.0%)	27/50 (54.0%)	20/46 (43.5%)
	Poly-K Incidence	33/40.4 (81.7%)	26/38.2 (68.1%)	27/38.7 (69.7%)	27/39.6 (68.2%)	27/38.7 (69.8%)	20/33.0 (60.6%)
	Terminal Incidence	13/15 (86.7%)	13/16 (81.3%)	10/17 (58.8%)	9/14 (64.3%)	12/16 (75.0%)	8/11 (72.7%)
	Time-to-First	520	516	484	485	526	509
	Poly-K P-Value	0.041N*	0.099N	0.133N	0.099N	0.131N	0.022N*
	Severity Profile	19 11 2 1	18 7 1 0	21 5 1 0	16 6 3 2	18 8 0 1	10 7 1 2
	JT/SW P-Value	0.060N	0.067N	0.066N	0.104N	0.094N	0.035N*
	RTE P-Value	0.063N	0.074N	0.067N	0.136N	0.077N	0.027N*
Prostate, Dorsal/Lateral Lobe * Inflammation,Suppurative	Simple Incidence	41/50 (82.0%)	46/48 (95.8%)	47/48 (97.9%)	45/50 (90.0%)	43/50 (86.0%)	41/46 (89.1%)
	Poly-K Incidence	41/45.6 (89.9%)	46/46.2 (99.6%)	47/48.0 (98.0%)	45/47.7 (94.4%)	43/46.5 (92.4%)	41/43.3 (94.6%)
	Terminal Incidence	14/15 (93.3%)	16/16 (100.0%)	17/17 (100.0%)	14/14 (100.0%)	15/16 (93.8%)	11/11 (100.0%)
	Time-to-First	284	176	284	244	348	304
	Poly-K P-Value	0.482N	0.027 *	0.084	0.316	0.475	0.305
	Severity Profile	8 26 4 3	10 26 9 1	9 30 8 0	17 24 2 2	8 28 6 1	12 20 6 3
	JT/SW P-Value	0.255N	0.909N	0.961N	0.238N	0.513N	0.620N
	RTE P-Value	0.265N	0.085	0.072	0.195N	0.365	0.364
Prostate, Ventral Lobe * Atrophy	Simple Incidence	4/50 (8.0%)	2/48 (4.2%)	2/48 (4.2%)	0/49 (0.0%)	5/49 (10.2%)	5/46 (10.9%)
	Poly-K Incidence	4/34.9 (11.5%)	2/34.6 (5.8%)	2/32.7 (6.1%)	0/32.9 (0.0%)	5/34.7 (14.4%)	5/29.7 (16.9%)
	Terminal Incidence	2/15 (13.3%)	0/16 (0.0%)	1/17 (5.9%)	0/14 (0.0%)	1/16 (6.3%)	2/11 (18.2%)
	Time-to-First	526	638	588	---	526	532
	Poly-K P-Value	0.171	0.338N	0.364N	0.066N	0.496	0.396
	Severity Profile	0 0 3 1	0 0 1 1	0 2 0 0	---	0 1 4 0	0 0 4 1
	JT/SW P-Value	0.178	0.779	0.877	0.968	0.429	0.379
	RTE P-Value	0.169	0.216N	0.161N	0.036N*	0.340	0.279
Prostate, Ventral Lobe * Fibrosis	Simple Incidence	15/50 (30.0%)	4/48 (8.3%)	6/48 (12.5%)	8/49 (16.3%)	4/49 (8.2%)	11/46 (23.9%)
	Poly-K Incidence	15/36.0 (41.7%)	4/34.6 (11.6%)	6/34.2 (17.6%)	8/34.6 (23.1%)	4/33.7 (11.9%)	11/31.6 (34.8%)
	Terminal Incidence	7/15 (46.7%)	2/16 (12.5%)	1/17 (5.9%)	3/14 (21.4%)	2/16 (12.5%)	2/11 (18.2%)
	Time-to-First	549	638	572	490	570	532
	Poly-K P-Value	0.274N	0.003N**	0.021N*	0.070N	0.004N**	0.365N
	Severity Profile	0 7 3 5	2 1 0 1	3 2 1 0	2 3 0 3	1 1 0 2	1 5 2 3
	JT/SW P-Value	0.226N	0.002N**	0.003N**	0.007N**	<.001N***	0.014N*
	RTE P-Value	0.264N	0.001N**	0.005N**	0.024N*	0.001N**	0.183N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 10. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Prostate, Ventral Lobe * Hyperplasia, Epithelium	Simple Incidence	10/50 (20.0%)	12/48 (25.0%)	10/48 (20.8%)	18/49 (36.7%)	12/49 (24.5%)	8/46 (17.4%)
	Poly-K Incidence	10/34.0 (29.4%)	12/36.4 (33.0%)	10/35.0 (28.5%)	18/36.3 (49.5%)	12/34.7 (34.6%)	8/30.5 (26.3%)
	Terminal Incidence	6/15 (40.0%)	5/16 (31.3%)	3/17 (17.6%)	5/14 (35.7%)	7/16 (43.8%)	3/11 (27.3%)
	Time-to-First	674	489	495	573	565	509
	Poly-K P-Value	0.406	0.471	0.576N	0.059	0.416	0.500N
	Severity Profile	1 6 3 0	2 6 3 1	2 4 4 0	1 13 3 1	3 6 3 0	2 2 2 2
	JT/SW P-Value	0.475	0.278	0.430	0.038 * ¹	0.165	0.325
	RTE P-Value	0.490	0.282	0.460	0.027 *	0.337	0.408N
Prostate, Ventral Lobe * Infiltration Cellular, Lymphocyte	Simple Incidence	25/50 (50.0%)	14/48 (29.2%)	15/48 (31.3%)	15/49 (30.6%)	20/49 (40.8%)	15/46 (32.6%)
	Poly-K Incidence	25/40.8 (61.2%)	14/38.2 (36.7%)	15/39.1 (38.3%)	15/39.4 (38.1%)	20/39.0 (51.3%)	15/33.3 (45.1%)
	Terminal Incidence	10/15 (66.7%)	7/16 (43.8%)	2/17 (11.8%)	2/14 (14.3%)	8/16 (50.0%)	5/11 (45.5%)
	Time-to-First	72	75	393	311	381	304
	Poly-K P-Value	0.255N	0.018N*	0.026N*	0.024N*	0.239N	0.109N
	Severity Profile	12 5 5 3	9 4 1 0	14 1 0 0	9 4 0 2	15 3 1 1	9 3 1 2
	JT/SW P-Value	0.121N	0.009N**	0.006N**	0.008N**	0.017N*	0.020N*
	RTE P-Value	0.136N	0.006N**	0.004N**	0.012N*	0.079N	0.023N*
Prostate, Ventral Lobe * Inflammation, Suppurative	Simple Incidence	16/50 (32.0%)	5/48 (10.4%)	5/48 (10.4%)	6/49 (12.2%)	5/49 (10.2%)	11/46 (23.9%)
	Poly-K Incidence	16/38.1 (42.0%)	5/34.6 (14.4%)	5/34.6 (14.4%)	6/35.3 (17.0%)	5/34.9 (14.3%)	11/31.9 (34.5%)
	Terminal Incidence	5/15 (33.3%)	3/16 (18.8%)	1/17 (5.9%)	2/14 (14.3%)	1/16 (6.3%)	4/11 (36.4%)
	Time-to-First	543	638	393	368	479	372
	Poly-K P-Value	0.176N	0.007N**	0.007N**	0.015N*	0.007N**	0.341N
	Severity Profile	7 2 2 5	3 2 0 0	3 2 0 0	3 1 0 2	1 2 1 1	5 2 1 3
	JT/SW P-Value	0.163N	0.003N**	0.002N**	0.002N**	0.001N**	0.007N**
	RTE P-Value	0.196N	0.002N**	0.002N**	0.003N**	0.002N**	0.126N
Prostate, Ventral Lobe * Mineralization	Simple Incidence	4/50 (8.0%)	1/48 (2.1%)	0/48 (0.0%)	1/49 (2.0%)	1/49 (2.0%)	0/46 (0.0%)
	Poly-K Incidence	4/34.0 (11.8%)	1/34.0 (2.9%)	0/32.3 (0.0%)	1/32.9 (3.0%)	1/33.1 (3.0%)	0/28.5 (0.0%)
	Terminal Incidence	2/15 (13.3%)	1/16 (6.3%)	0/17 (0.0%)	1/14 (7.1%)	1/16 (6.3%)	0/11 (0.0%)
	Time-to-First	671	724 (T)	----	726 (T)	727 (T)	----
	Poly-K P-Value	0.028N*	0.175N	0.065N	0.185N	0.183N	0.083N
	Severity Profile	0 0 3 1	1 0 0 0	---	1 0 0 0	0 1 0 0	---
	JT/SW P-Value	0.017N*	0.087N	0.016N*	0.025N*	0.027N*	0.006N**
	RTE P-Value	0.016N*	0.012N*	0.002N**	0.010N*	0.011N*	0.002N**

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 10. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Seminal Vesicle * Dilatation,Lumen	Simple Incidence	2/44 (4.5%)	2/42 (4.8%)	4/45 (8.9%)	2/41 (4.9%)	0/44 (0.0%)	1/43 (2.3%)
	Poly-K Incidence	2/31.7 (6.3%)	2/31.3 (6.4%)	4/32.7 (12.2%)	2/29.1 (6.9%)	0/30.3 (0.0%)	1/26.8 (3.7%)
	Terminal Incidence	1/15 (6.7%)	1/16 (6.3%)	1/17 (5.9%)	2/14 (14.3%)	0/16 (0.0%)	0/11 (0.0%)
	Time-to-First	720	452	338	726 (T)	----	699
	Poly-K P-Value	0.184N	0.691	0.348	0.664	0.246N	0.559N
	Severity Profile	0 0 0 2	0 0 0 2	0 2 0 2	0 0 2 0	---	0 0 0 1
	JT/SW P-Value	0.120N	0.519N	0.757N	0.627N	0.199N	0.289N
	RTE P-Value	0.126N	0.480	0.221	0.485	0.118N	0.302N
Seminal Vesicle * Hyperplasia,Epithelium	Simple Incidence	7/44 (15.9%)	6/42 (14.3%)	5/45 (11.1%)	3/41 (7.3%)	4/44 (9.1%)	3/43 (7.0%)
	Poly-K Incidence	7/32.7 (21.4%)	6/30.7 (19.5%)	5/31.7 (15.8%)	3/29.6 (10.1%)	4/31.1 (12.9%)	3/27.3 (11.0%)
	Terminal Incidence	5/15 (33.3%)	5/16 (31.3%)	4/17 (23.5%)	1/14 (7.1%)	3/16 (18.8%)	1/11 (9.1%)
	Time-to-First	558	680	412	600	443	644
	Poly-K P-Value	0.082N	0.550N	0.397N	0.190N	0.282N	0.231N
	Severity Profile	0 5 1 1	0 3 3 0	0 4 0 1	0 1 1 1	0 1 3 0	0 1 2 0
	JT/SW P-Value	0.061N	0.434N	0.304N	0.161N	0.193N	0.132N
	RTE P-Value	0.062N	0.418N	0.236N	0.121N	0.184N	0.108N
Testes * Degeneration,Seminiferous Tubule	Simple Incidence	40/49 (81.6%)	30/48 (62.5%)	33/48 (68.8%)	35/50 (70.0%)	38/50 (76.0%)	33/46 (71.7%)
	Poly-K Incidence	40/44.6 (89.8%)	30/40.7 (73.8%)	33/41.3 (80.0%)	35/42.6 (82.1%)	38/45.5 (83.5%)	33/40.6 (81.3%)
	Terminal Incidence	14/15 (93.3%)	13/16 (81.3%)	13/17 (76.5%)	11/14 (78.6%)	12/16 (75.0%)	9/11 (81.8%)
	Time-to-First	225	452	284	342	348	304
	Poly-K P-Value	0.387N	0.030N*	0.127N	0.199N	0.260N	0.174N
	Severity Profile	20 5 5 10	15 5 0 10	11 11 2 9	9 8 4 14	17 10 1 10	20 3 2 8
	JT/SW P-Value	0.364N	0.055N	0.159N	0.323N	0.362N	0.144N
	RTE P-Value	0.365N	0.061N	0.260N	0.458	0.342N	0.108N
Testes * Polyarteritis	Simple Incidence	12/49 (24.5%)	11/48 (22.9%)	16/48 (33.3%)	20/50 (40.0%)	16/50 (32.0%)	10/46 (21.7%)
	Poly-K Incidence	12/35.2 (34.1%)	11/35.6 (30.9%)	16/34.8 (46.0%)	20/37.8 (53.0%)	16/37.0 (43.2%)	10/29.7 (33.7%)
	Terminal Incidence	6/15 (40.0%)	5/16 (31.3%)	8/17 (47.1%)	8/14 (57.1%)	7/16 (43.8%)	6/11 (54.5%)
	Time-to-First	494	553	572	490	443	534
	Poly-K P-Value	0.211	0.488N	0.208	0.070	0.282	0.595N
	Severity Profile	1 5 1 5	2 4 4 1	3 8 1 4	2 8 6 4	5 3 5 3	4 3 1 2
	JT/SW P-Value	0.425	0.629	0.264	0.070	0.182	0.365
	RTE P-Value	0.442	0.369N	0.229	0.054	0.267	0.286N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 10. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Hematopoietic System							
Bone Marrow * Hyperplasia, Myeloid Cell	Simple Incidence	6/48 (12.5%)	4/48 (8.3%)	2/48 (4.2%)	3/49 (6.1%)	7/50 (14.0%)	2/45 (4.4%)
	Poly-K Incidence	6/35.1 (17.1%)	4/35.4 (11.3%)	2/33.0 (6.1%)	3/34.2 (8.8%)	7/34.6 (20.2%)	2/29.6 (6.8%)
	Terminal Incidence	1/15 (6.7%)	1/16 (6.3%)	0/17 (0.0%)	0/14 (0.0%)	4/16 (25.0%)	0/11 (0.0%)
	Time-to-First	520	539	547	573	541	532
	Poly-K P-Value	0.360N	0.361N	0.148N	0.249N	0.488	0.188N
	Severity Profile	0 1 1 4	0 0 1 3	0 0 0 2	0 0 3 0	0 0 2 5	0 0 0 2
	JT/SW P-Value	0.289N	0.260N	0.089N	0.109N	0.302N	0.112N
	RTE P-Value	0.268N	0.237N	0.092N	0.103N	0.387	0.096N
Bone Marrow * Hypocellularity	Simple Incidence	5/48 (10.4%)	7/48 (14.6%)	5/48 (10.4%)	0/49 (0.0%)	0/50 (0.0%)	4/45 (8.9%)
	Poly-K Incidence	5/33.3 (15.0%)	7/35.1 (19.9%)	5/33.3 (15.0%)	0/32.9 (0.0%)	0/33.6 (0.0%)	4/29.0 (13.8%)
	Terminal Incidence	3/15 (20.0%)	3/16 (18.8%)	3/17 (17.6%)	0/14 (0.0%)	0/16 (0.0%)	2/11 (18.2%)
	Time-to-First	616	613	568	----	----	637
	Poly-K P-Value	0.025N*	0.413	0.634	0.029N*	0.028N*	0.591N
	Severity Profile	0 0 5 0	0 0 4 3	0 0 4 1	---	---	0 0 2 2
	JT/SW P-Value	0.023N*	0.761N	0.599N	0.047N* ¹	0.029N* ¹	0.114N
	RTE P-Value	0.026N*	0.160	0.488	0.032N*	0.031N*	0.413N
Spleen * Hematopoietic Cell Proliferation	Simple Incidence	13/49 (26.5%)	10/47 (21.3%)	13/48 (27.1%)	11/47 (23.4%)	10/49 (20.4%)	13/45 (28.9%)
	Poly-K Incidence	13/37.2 (35.0%)	10/35.2 (28.4%)	13/37.0 (35.2%)	11/36.6 (30.1%)	10/35.3 (28.3%)	13/33.5 (38.8%)
	Terminal Incidence	4/15 (26.7%)	5/16 (31.3%)	2/17 (11.8%)	1/14 (7.1%)	4/16 (25.0%)	2/11 (18.2%)
	Time-to-First	225	539	284	490	513	386
	Poly-K P-Value	0.450	0.363N	0.590	0.419N	0.358N	0.465
	Severity Profile	5 3 3 2	5 4 1 0	6 2 2 3	4 5 0 2	4 5 0 1	2 8 3 0
	JT/SW P-Value	0.447	0.776	0.566	0.693	0.793	0.504
	RTE P-Value	0.432	0.225N	0.487	0.342N	0.212N	0.378
Spleen * Pigmentation	Simple Incidence	28/49 (57.1%)	28/47 (59.6%)	28/48 (58.3%)	23/47 (48.9%)	22/49 (44.9%)	24/45 (53.3%)
	Poly-K Incidence	28/40.3 (69.4%)	28/41.0 (68.4%)	28/39.8 (70.4%)	23/38.0 (60.5%)	22/38.7 (56.9%)	24/36.5 (65.7%)
	Terminal Incidence	12/15 (80.0%)	10/16 (62.5%)	12/17 (70.6%)	11/14 (78.6%)	9/16 (56.3%)	9/11 (81.8%)
	Time-to-First	284	292	412	244	381	311
	Poly-K P-Value	0.151N	0.557N	0.565	0.259N	0.160N	0.454N
	Severity Profile	5 15 4 4	5 13 8 2	7 14 6 1	8 9 5 1	5 10 5 2	4 15 5 0
	JT/SW P-Value	0.074N	0.618N	0.488N	0.154N	0.149N	0.222N
	RTE P-Value	0.079N	0.377	0.424N	0.123N	0.116N	0.284N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 10. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Continuous Dose Arm							
System and Nonneoplasm	Treatment (ug/kg)						
Lesion	Statistic	Control	2.5	25	250	2500	25000
Thymus * Atrophy	Simple Incidence	47/50 (94.0%)	43/46 (93.5%)	44/46 (95.7%)	47/49 (95.9%)	47/49 (95.9%)	42/43 (97.7%)
	Poly-K Incidence	47/48.2 (97.5%)	43/43.5 (98.9%)	44/44.7 (98.4%)	47/47.5 (98.9%)	47/47.2 (99.6%)	42/42.5 (98.9%)
	Terminal Incidence	15/15 (100.0%)	16/16 (100.0%)	17/17 (100.0%)	14/14 (100.0%)	16/16 (100.0%)	11/11 (100.0%)
	Time-to-First	225	418	284	244	381	311
	Poly-K P-Value	0.217	0.625	0.692	0.611	0.486	0.631
	Severity Profile	0 2 1 44	0 0 0 43	0 0 2 42	0 4 1 42	0 0 3 44	0 0 1 41
	JT/SW P-Value	0.277	0.198	0.281	0.464	0.478	0.148
	RTE P-Value	0.269	0.211	0.283	0.361N	0.362	0.113
Integumentary System							
Mammary Gland * Degeneration,Alveolus	Simple Incidence	28/50 (56.0%)	22/48 (45.8%)	25/48 (52.1%)	22/50 (44.0%)	25/50 (50.0%)	23/45 (51.1%)
	Poly-K Incidence	28/40.6 (69.0%)	22/40.4 (54.4%)	25/40.7 (61.5%)	22/40.0 (55.0%)	25/40.6 (61.5%)	23/34.5 (66.6%)
	Terminal Incidence	11/15 (73.3%)	11/16 (68.8%)	9/17 (52.9%)	7/14 (50.0%)	11/16 (68.8%)	7/10 (70.0%)
	Time-to-First	284	176	393	368	348	372
	Poly-K P-Value	0.508N	0.116N	0.306N	0.129N	0.307N	0.513N
	Severity Profile	0 1 10 17	0 3 4 15	0 9 5 11	0 2 6 14	0 2 9 14	0 3 7 13
	JT/SW P-Value	0.317N	0.193N	0.172N	0.156N	0.216N	0.253N
	RTE P-Value	0.327N	0.174N	0.146N	0.123N	0.237N	0.263N
Mammary Gland * Dilatation,Alveolus	Simple Incidence	8/50 (16.0%)	17/48 (35.4%)	11/48 (22.9%)	10/50 (20.0%)	11/50 (22.0%)	9/45 (20.0%)
	Poly-K Incidence	8/35.0 (22.9%)	17/36.8 (46.2%)	11/34.7 (31.7%)	10/34.6 (28.9%)	11/36.1 (30.5%)	9/29.5 (30.5%)
	Terminal Incidence	3/15 (20.0%)	5/16 (31.3%)	4/17 (23.5%)	6/14 (42.9%)	3/16 (18.8%)	3/10 (30.0%)
	Time-to-First	558	613	572	582	566	596
	Poly-K P-Value	0.413N	0.028 *	0.283	0.380	0.321	0.339
	Severity Profile	0 5 3 0	0 10 6 1	0 4 6 1	0 8 2 0	0 7 4 0	0 8 0 1
	JT/SW P-Value	0.285N	0.986N	0.896N	0.766N	0.836N	0.788N
	RTE P-Value	0.267N	0.011 *	0.166	0.351	0.241	0.363
Mammary Gland * Dilatation,Duct	Simple Incidence	14/50 (28.0%)	18/48 (37.5%)	15/48 (31.3%)	11/50 (22.0%)	15/50 (30.0%)	11/45 (24.4%)
	Poly-K Incidence	14/35.7 (39.2%)	18/36.8 (49.0%)	15/37.1 (40.4%)	11/35.2 (31.3%)	15/36.6 (41.0%)	11/30.4 (36.2%)
	Terminal Incidence	6/15 (40.0%)	6/16 (37.5%)	3/17 (17.6%)	6/14 (42.9%)	6/16 (37.5%)	3/10 (30.0%)
	Time-to-First	549	613	412	556	566	501
	Poly-K P-Value	0.247N	0.265	0.554	0.321N	0.536	0.500N
	Severity Profile	0 8 6 0	0 7 8 3	0 6 7 2	0 6 5 0	0 4 11 0	0 7 3 1
	JT/SW P-Value	0.194N	0.895N	0.795N	0.350N	0.610N	0.478N
	RTE P-Value	0.187N	0.100	0.289	0.273N	0.318	0.357N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 10. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Nervous System							
Brain, Brain Stem * Compression	Simple Incidence	12/49 (24.5%)	14/48 (29.2%)	12/48 (25.0%)	10/49 (20.4%)	9/49 (18.4%)	8/46 (17.4%)
	Poly-K Incidence	12/35.7 (33.6%)	14/36.8 (38.0%)	12/36.1 (33.3%)	10/35.6 (28.1%)	9/35.4 (25.4%)	8/30.3 (26.4%)
	Terminal Incidence	4/15 (26.7%)	3/16 (18.8%)	3/17 (17.6%)	4/14 (28.6%)	2/16 (12.5%)	3/11 (27.3%)
	Time-to-First	558	613	559	490	566	501
	Poly-K P-Value	0.117N	0.440	0.588N	0.399N	0.305N	0.355N
	Severity Profile	3 2 4 3	1 3 7 3	1 5 5 1	3 3 3 1	1 2 3 3	1 2 4 1
	JT/SW P-Value	0.073N	0.727N	0.579N	0.353N	0.352N	0.281N
	RTE P-Value	0.071N	0.258	0.498	0.275N	0.262N	0.209N
Brain, Cerebrum * Dilatation,Ventricle	Simple Incidence	6/50 (12.0%)	10/48 (20.8%)	8/48 (16.7%)	5/49 (10.2%)	6/49 (12.2%)	4/46 (8.7%)
	Poly-K Incidence	6/35.8 (16.7%)	10/36.2 (27.6%)	8/35.1 (22.8%)	5/34.6 (14.5%)	6/34.9 (17.2%)	4/29.8 (13.4%)
	Terminal Incidence	0/15 (0.0%)	1/16 (6.3%)	1/17 (5.9%)	1/14 (7.1%)	1/16 (6.3%)	1/11 (9.1%)
	Time-to-First	558	619	559	582	566	501
	Poly-K P-Value	0.177N	0.201	0.365	0.526N	0.606	0.489N
	Severity Profile	2 4 0 0	6 3 1 0	7 0 1 0	2 2 1 0	3 3 0 0	1 3 0 0
	JT/SW P-Value	0.130N	0.866N	0.770N	0.504N	0.578N	0.430N
	RTE P-Value	0.132N	0.113	0.294	0.398N	0.500N	0.320N
Brain, Cerebrum * Hemorrhage	Simple Incidence	2/50 (4.0%)	0/48 (0.0%)	0/48 (0.0%)	1/49 (2.0%)	1/49 (2.0%)	4/46 (8.7%)
	Poly-K Incidence	2/35.1 (5.7%)	0/34.0 (0.0%)	0/32.3 (0.0%)	1/33.7 (3.0%)	1/33.9 (3.0%)	4/30.6 (13.1%)
	Terminal Incidence	0/15 (0.0%)	0/16 (0.0%)	0/17 (0.0%)	0/14 (0.0%)	0/16 (0.0%)	0/11 (0.0%)
	Time-to-First	486	---	---	582	443	311
	Poly-K P-Value	0.077	0.243N	0.255N	0.514N	0.512N	0.272
	Severity Profile	1 1 0 0	---	---	0 1 0 0	0 0 0 1	1 2 1 0
	JT/SW P-Value	0.065	0.918	0.982	0.886	0.892	0.104
	RTE P-Value	0.051	0.108N	0.111N	0.279N	0.284N	0.051
Urinary System							
Kidney * Cyst,Cortex	Simple Incidence	20/50 (40.0%)	15/48 (31.3%)	13/48 (27.1%)	10/50 (20.0%)	15/50 (30.0%)	11/45 (24.4%)
	Poly-K Incidence	20/37.8 (53.0%)	15/35.5 (42.3%)	13/36.7 (35.4%)	10/35.2 (28.4%)	15/37.2 (40.3%)	11/32.6 (33.7%)
	Terminal Incidence	9/15 (60.0%)	9/16 (56.3%)	4/17 (23.5%)	4/14 (28.6%)	9/16 (56.3%)	2/11 (18.2%)
	Time-to-First	494	585	412	573	348	330
	Poly-K P-Value	0.049N*	0.237N	0.087N	0.022N*	0.180N	0.072N
Kidney * Cyst,Renal Tubule	Simple Incidence	11/50 (22.0%)	13/48 (27.1%)	15/48 (31.3%)	21/50 (42.0%)	20/50 (40.0%)	11/45 (24.4%)
	Poly-K Incidence	11/37.4 (29.4%)	13/37.3 (34.8%)	15/38.0 (39.5%)	21/39.6 (53.1%)	20/38.7 (51.7%)	11/32.3 (34.0%)
	Terminal Incidence	3/15 (20.0%)	5/16 (31.3%)	4/17 (23.5%)	9/14 (64.3%)	8/16 (50.0%)	4/11 (36.4%)
	Time-to-First	284	75	412	368	411	372
	Poly-K P-Value	0.068	0.400	0.244	0.024 *	0.033 *	0.438

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 10. Nonneoplasms by Body System for Terminal Sacrifice Males Bisphenol-A Continuous Dose Arm</i>							
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>						
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>2.5</i>	<i>25</i>	<i>250</i>	<i>2500</i>	<i>25000</i>
Kidney * Hyperplasia, Transitional Epithelium	Simple Incidence	3/50 (6.0%)	4/48 (8.3%)	12/48 (25.0%)	7/50 (14.0%)	5/50 (10.0%)	4/45 (8.9%)
	Poly-K Incidence	3/34.6 (8.7%)	4/34.5 (11.6%)	12/34.1 (35.2%)	7/34.8 (20.1%)	5/34.1 (14.7%)	4/28.9 (13.8%)
	Terminal Incidence	1/15 (6.7%)	1/16 (6.3%)	7/17 (41.2%)	3/14 (21.4%)	2/16 (12.5%)	2/11 (18.2%)
	Time-to-First	543	650	576	490	645	650
	Poly-K P-Value	0.331	0.498	0.006 **	0.151	0.344	0.400
	Severity Profile	1 1 1 0	1 3 0 0	5 6 1 0	5 1 0 1	2 2 1 0	1 1 1 1
	JT/SW P-Value	0.394	0.334	0.003 ** ¹	0.033 * ¹	0.086	0.142
	RTE P-Value	0.405	0.364	0.002 **	0.130	0.272	0.318
Kidney * Infiltration Cellular, Polymorphonuclear	Simple Incidence	6/50 (12.0%)	6/48 (12.5%)	5/48 (10.4%)	8/50 (16.0%)	6/50 (12.0%)	3/45 (6.7%)
	Poly-K Incidence	6/35.3 (17.0%)	6/34.3 (17.5%)	5/32.7 (15.3%)	8/34.4 (23.3%)	6/34.0 (17.7%)	3/28.7 (10.5%)
	Terminal Incidence	3/15 (20.0%)	4/16 (25.0%)	3/17 (17.6%)	5/14 (35.7%)	3/16 (18.8%)	2/11 (18.2%)
	Time-to-First	543	678	618	622	677	650
	Poly-K P-Value	0.393N	0.604	0.555N	0.360	0.598	0.348N
	Severity Profile	4 1 1 0	2 4 0 0	1 4 0 0	4 4 0 0	2 4 0 0	3 0 0 0
	JT/SW P-Value	0.283N	0.550N	0.507N	0.700N	0.659N	0.270N
	RTE P-Value	0.269N	0.449	0.432N	0.265	0.480	0.195N
Kidney * Mineralization	Simple Incidence	1/50 (2.0%)	3/48 (6.3%)	3/48 (6.3%)	5/50 (10.0%)	1/50 (2.0%)	1/45 (2.2%)
	Poly-K Incidence	1/34.1 (2.9%)	3/35.0 (8.6%)	3/33.7 (8.9%)	5/35.3 (14.2%)	1/33.9 (2.9%)	1/28.6 (3.5%)
	Terminal Incidence	0/15 (0.0%)	0/16 (0.0%)	0/17 (0.0%)	0/14 (0.0%)	0/16 (0.0%)	0/11 (0.0%)
	Time-to-First	633	489	572	490	637	671
	Poly-K P-Value	0.482N	0.314	0.299	0.105	0.761	0.723
	Severity Profile	0 0 0 1	2 0 1 0	0 1 1 1	0 2 2 1	0 0 1 0	0 1 0 0
	JT/SW P-Value	0.397N	0.848N	0.898N	0.946N	0.630N	0.650N
	RTE P-Value	0.379N	0.220	0.177	0.035 *	0.495N	0.491
Kidney * Nephropathy	Simple Incidence	44/50 (88.0%)	44/48 (91.7%)	43/48 (89.6%)	45/50 (90.0%)	47/50 (94.0%)	39/45 (86.7%)
	Poly-K Incidence	44/46.4 (94.8%)	44/45.4 (97.0%)	43/44.2 (97.2%)	45/46.3 (97.1%)	47/47.5 (99.0%)	39/40.4 (96.5%)
	Terminal Incidence	15/15 (100.0%)	16/16 (100.0%)	17/17 (100.0%)	14/14 (100.0%)	16/16 (100.0%)	11/11 (100.0%)
	Time-to-First	225	292	393	244	381	383
	Poly-K P-Value	0.193	0.502	0.472	0.480	0.222	0.578
	Severity Profile	11 12 6 15	12 7 7 18	10 8 6 19	5 11 13 16	4 13 13 17	12 11 10 6
	JT/SW P-Value	0.320N	0.768N	0.860N	0.918N	0.957N	0.157N
	RTE P-Value	0.297N	0.209	0.178	0.109	0.045 *	0.107N

P-values for dose trend are presented in the “Control” column.

N indicates a negative trend or negative treatment comparison to control with corresponding lower-tail p-values.

¹ Nonsignificant SW test due to the assumption of monotonicity.

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 11. Nonneoplasms by Body System for Terminal Sacrifice Females EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Alimentary System				
Liver * Basophilic Focus	Simple Incidence	18/50 (36.0%)	12/26 (46.2%)	14/26 (53.8%)
	Poly-K Incidence	18/40.1 (44.9%)	12/18.9 (63.5%)	14/20.8 (67.4%)
	Terminal Incidence	5/16 (31.3%)	5/7 (71.4%)	2/4 (50.0%)
	Time-to-First	488	505	488
	Poly-K P-Value	0.036 *	0.134	0.068
Liver * Clear Cell Focus	Simple Incidence	9/50 (18.0%)	2/26 (7.7%)	1/26 (3.8%)
	Poly-K Incidence	9/36.7 (24.5%)	2/15.9 (12.6%)	1/15.7 (6.4%)
	Terminal Incidence	4/16 (25.0%)	2/7 (28.6%)	0/4 (0.0%)
	Time-to-First	496	724 (T)	525
	Poly-K P-Value	0.068N	0.274N	0.128N
Liver * Cyst,Biliary Tract	Simple Incidence	0/50 (0.0%)	2/26 (7.7%)	0/26 (0.0%)
	Poly-K Incidence	0/34.2 (0.0%)	2/15.9 (12.6%)	0/15.1 (0.0%)
	Terminal Incidence	0/16 (0.0%)	2/7 (28.6%)	0/4 (0.0%)
	Time-to-First	----	728 (T)	----
	Poly-K P-Value	0.444	0.090	-----
Liver * Degeneration,Cystic	Simple Incidence	4/50 (8.0%)	4/26 (15.4%)	2/26 (7.7%)
	Poly-K Incidence	4/34.9 (11.5%)	4/17.3 (23.1%)	2/15.2 (13.2%)
	Terminal Incidence	2/16 (12.5%)	0/7 (0.0%)	1/4 (25.0%)
	Time-to-First	620	511	711
	Poly-K P-Value	0.414	0.244	0.615
	Severity Profile	4 0 0 0	4 0 0 0	1 1 0 0
	JT/SW P-Value	0.385	0.161	0.363
	RTE P-Value	0.496	0.161	0.496
Liver * Fatty Change	Simple Incidence	19/50 (38.0%)	5/26 (19.2%)	3/26 (11.5%)
	Poly-K Incidence	19/40.4 (47.1%)	5/17.9 (28.0%)	3/15.7 (19.1%)
	Terminal Incidence	5/16 (31.3%)	1/7 (14.3%)	1/4 (25.0%)
	Time-to-First	488	490	571
	Poly-K P-Value	0.023N*	0.138N	0.053N
	Severity Profile	3 6 8 2	0 4 1 0	1 2 0 0
	JT/SW P-Value	0.002N**	0.039N*	0.004N**
	RTE P-Value	0.002N**	0.026N*	0.002N**

RR9: CLARITY-BPA Core Study

Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 11. Nonneoplasms by Body System for Terminal Sacrifice Females EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Liver * Fibrosis,Biliary Tract	Simple Incidence	6/50 (12.0%)	3/26 (11.5%)	0/26 (0.0%)
	Poly-K Incidence	6/34.8 (17.3%)	3/16.9 (17.8%)	0/15.1 (0.0%)
	Terminal Incidence	4/16 (25.0%)	1/7 (14.3%)	0/4 (0.0%)
	Time-to-First	625	579	----
	Poly-K P-Value	0.119N	0.635	0.110N
	Severity Profile	3 3 0 0	3 0 0 0	---
	JT/SW P-Value	0.056N	0.442N	0.045N*
	RTE P-Value	0.029N*	0.443N	0.029N*
Liver * Hematopoietic Cell Proliferation	Simple Incidence	2/50 (4.0%)	2/26 (7.7%)	0/26 (0.0%)
	Poly-K Incidence	2/35.6 (5.6%)	2/16.6 (12.0%)	0/15.1 (0.0%)
	Terminal Incidence	0/16 (0.0%)	1/7 (14.3%)	0/4 (0.0%)
	Time-to-First	477	497	----
	Poly-K P-Value	0.469N	0.402	0.443N
	Severity Profile	2 0 0 0	2 0 0 0	---
	JT/SW P-Value	0.300N	0.752N	0.237N
	RTE P-Value	0.220N	0.218	0.220N
Liver * Hepatodiaphragmatic Nodule	Simple Incidence	6/50 (12.0%)	0/26 (0.0%)	0/26 (0.0%)
	Poly-K Incidence	6/35.3 (17.0%)	0/15.9 (0.0%)	0/15.1 (0.0%)
	Terminal Incidence	4/16 (25.0%)	0/7 (0.0%)	0/4 (0.0%)
	Time-to-First	488	----	----
	Poly-K P-Value	0.025N*	0.102N	0.114N
Liver * Hyperplasia,Bile Duct	Simple Incidence	16/50 (32.0%)	8/26 (30.8%)	1/26 (3.8%)
	Poly-K Incidence	16/37.8 (42.3%)	8/18.5 (43.2%)	1/15.4 (6.5%)
	Terminal Incidence	8/16 (50.0%)	2/7 (28.6%)	0/4 (0.0%)
	Time-to-First	431	460	631
	Poly-K P-Value	0.022N*	0.591	0.011N*
	Severity Profile	7 6 3 0	4 4 0 0	0 1 0 0
	JT/SW P-Value	0.008N**	0.405N	0.004N**
	RTE P-Value	0.002N**	0.406N	0.002N**
Liver * Infiltration Cellular,Mononuclear Cell	Simple Incidence	37/50 (74.0%)	17/26 (65.4%)	10/26 (38.5%)
	Poly-K Incidence	37/44.3 (83.4%)	17/21.6 (78.7%)	10/18.7 (53.5%)
	Terminal Incidence	16/16 (100.0%)	6/7 (85.7%)	2/4 (50.0%)
	Time-to-First	431	443	486
	Poly-K P-Value	0.006N**	0.441N	0.006N**
	Severity Profile	27 9 1 0	15 2 0 0	8 2 0 0
	JT/SW P-Value	0.001N**	0.100N	0.001N**
	RTE P-Value	<.001N***	0.108N	<.001N***

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 11. Nonneoplasms by Body System for Terminal Sacrifice Females EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Liver * Tension Lipidosis	Simple Incidence	5/50 (10.0%)	2/26 (7.7%)	7/26 (26.9%)
	Poly-K Incidence	5/35.9 (13.9%)	2/16.6 (12.1%)	7/16.9 (41.5%)
	Terminal Incidence	2/16 (12.5%)	0/7 (0.0%)	2/4 (50.0%)
	Time-to-First	496	614	525
	Poly-K P-Value	0.024 *	0.597N	0.026 *
	Severity Profile	0 1 1 3	0 0 1 1	0 1 4 2
	JT/SW P-Value	0.053	0.628	0.030 *
	RTE P-Value	0.026 *	0.390N	0.026 *
Liver * Vacuolization Cytoplasmic	Simple Incidence	11/50 (22.0%)	11/26 (42.3%)	7/26 (26.9%)
	Poly-K Incidence	11/37.0 (29.8%)	11/19.1 (57.7%)	7/17.5 (40.1%)
	Terminal Incidence	4/16 (25.0%)	5/7 (71.4%)	2/4 (50.0%)
	Time-to-First	450	497	360
	Poly-K P-Value	0.151	0.031 *	0.324
	Severity Profile	4 7 0 0	8 3 0 0	5 1 1 0
	JT/SW P-Value	0.258	0.065	0.216
	RTE P-Value	0.391	0.067	0.391
Pancreas * Basophilic Focus	Simple Incidence	3/50 (6.0%)	3/26 (11.5%)	0/26 (0.0%)
	Poly-K Incidence	3/35.0 (8.6%)	3/16.8 (17.8%)	0/15.1 (0.0%)
	Terminal Incidence	0/16 (0.0%)	1/7 (14.3%)	0/4 (0.0%)
	Time-to-First	569	490	----
	Poly-K P-Value	0.395N	0.307	0.306N
Pancreas * Degeneration,Acinus	Simple Incidence	34/50 (68.0%)	18/26 (69.2%)	16/26 (61.5%)
	Poly-K Incidence	34/43.4 (78.3%)	18/23.7 (76.1%)	16/22.4 (71.4%)
	Terminal Incidence	15/16 (93.8%)	4/7 (57.1%)	2/4 (50.0%)
	Time-to-First	450	443	462
	Poly-K P-Value	0.306N	0.541N	0.360N
	Severity Profile	5 16 8 5	4 10 2 2	7 6 1 2
	JT/SW P-Value	0.068N	0.304N	0.073N
	RTE P-Value	0.065N	0.321N	0.065N
Pancreas * Hyperplasia,Acinar Cell	Simple Incidence	0/50 (0.0%)	0/26 (0.0%)	2/26 (7.7%)
	Poly-K Incidence	0/34.2 (0.0%)	0/15.9 (0.0%)	2/16.1 (12.5%)
	Terminal Incidence	0/16 (0.0%)	0/7 (0.0%)	0/4 (0.0%)
	Time-to-First	----	----	527
	Poly-K P-Value	0.038 *	-----	0.091
	Severity Profile	---	---	0 0 0 2
	JT/SW P-Value	0.023 *	0.500	0.013 *
	RTE P-Value	0.032 *	0.500	0.032 *

RR9: CLARITY-BPA Core Study

Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 11. Nonneoplasms by Body System for Terminal Sacrifice Females EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Pancreas * Infiltration Cellular,Lymphocyte	Simple Incidence	35/50 (70.0%)	18/26 (69.2%)	13/26 (50.0%)
	Poly-K Incidence	35/43.1 (81.1%)	18/22.6 (79.5%)	13/20.7 (62.7%)
	Terminal Incidence	15/16 (93.8%)	5/7 (71.4%)	2/4 (50.0%)
	Time-to-First	477	443	462
	Poly-K P-Value	0.066N	0.579N	0.072N
	Severity Profile	16 17 2 0	13 4 1 0	8 3 2 0
	JT/SW P-Value	0.029N*	0.166N	0.037N*
	RTE P-Value	0.031N*	0.189N	0.031N*
Pancreas * Lipomatosis	Simple Incidence	6/50 (12.0%)	1/26 (3.8%)	0/26 (0.0%)
	Poly-K Incidence	6/35.6 (16.8%)	1/15.9 (6.3%)	0/15.1 (0.0%)
	Terminal Incidence	2/16 (12.5%)	1/7 (14.3%)	0/4 (0.0%)
	Time-to-First	506	728 (T)	----
	Poly-K P-Value	0.052N	0.284N	0.116N
	Severity Profile	0 1 3 2	0 0 1 0	---
	JT/SW P-Value	0.019N*	0.121N	0.029N*
	RTE P-Value	0.015N*	0.077N	0.015N*
Pancreas * Pigmentation	Simple Incidence	11/50 (22.0%)	4/26 (15.4%)	5/26 (19.2%)
	Poly-K Incidence	11/38.6 (28.5%)	4/18.0 (22.2%)	5/18.1 (27.7%)
	Terminal Incidence	3/16 (18.8%)	0/7 (0.0%)	0/4 (0.0%)
	Time-to-First	450	484	462
	Poly-K P-Value	0.499N	0.431N	0.600N
	Severity Profile	10 1 0 0	4 0 0 0	4 1 0 0
	JT/SW P-Value	0.341N	0.238N	0.377N
	RTE P-Value	0.405N	0.241N	0.405N
Cardiovascular System				
Heart * Cardiomyopathy	Simple Incidence	35/50 (70.0%)	19/26 (73.1%)	22/26 (84.6%)
	Poly-K Incidence	35/43.5 (80.6%)	19/22.6 (84.2%)	22/24.0 (91.7%)
	Terminal Incidence	15/16 (93.8%)	6/7 (85.7%)	4/4 (100.0%)
	Time-to-First	446	484	360
	Poly-K P-Value	0.112	0.488	0.149
	Severity Profile	24 10 1 0	14 5 0 0	12 9 1 0
	JT/SW P-Value	0.057	0.498	0.042 *
	RTE P-Value	0.035 *	0.493N	0.035 *

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 11. Nonneoplasms by Body System for Terminal Sacrifice Females EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Endocrine System				
Adrenal Cortex * Angiectasis	Simple Incidence	9/50 (18.0%)	3/26 (11.5%)	9/26 (34.6%)
	Poly-K Incidence	9/37.3 (24.1%)	3/17.2 (17.4%)	9/18.7 (48.1%)
	Terminal Incidence	2/16 (12.5%)	0/7 (0.0%)	1/4 (25.0%)
	Time-to-First	496	505	462
	Poly-K P-Value	0.057	0.420N	0.057
	Severity Profile	0 4 3 2	0 3 0 0	0 1 2 6
	JT/SW P-Value	0.066	0.804	0.027 *
	RTE P-Value	0.024 *	0.223N	0.024 *
Adrenal Cortex * Degeneration,Cystic	Simple Incidence	31/50 (62.0%)	13/26 (50.0%)	22/26 (84.6%)
	Poly-K Incidence	31/42.0 (73.8%)	13/19.9 (65.3%)	22/23.2 (94.6%)
	Terminal Incidence	13/16 (81.3%)	6/7 (85.7%)	4/4 (100.0%)
	Time-to-First	450	484	462
	Poly-K P-Value	0.026 *	0.331N	0.017 *
	Severity Profile	3 10 8 10	2 6 3 2	3 4 0 15
	JT/SW P-Value	0.032 *	0.925	0.005 **
	RTE P-Value	0.003 **	0.077N	0.003 **
Adrenal Cortex * Hyperplasia	Simple Incidence	7/50 (14.0%)	4/26 (15.4%)	1/26 (3.8%)
	Poly-K Incidence	7/36.7 (19.1%)	4/17.0 (23.5%)	1/15.1 (6.6%)
	Terminal Incidence	2/16 (12.5%)	2/7 (28.6%)	0/4 (0.0%)
	Time-to-First	450	511	716
	Poly-K P-Value	0.275N	0.497	0.247N
	Severity Profile	3 3 1 0	1 3 0 0	1 0 0 0
	JT/SW P-Value	0.134N	0.571N	0.108N
	RTE P-Value	0.091N	0.423	0.091N
Adrenal Cortex * Hypertrophy	Simple Incidence	5/50 (10.0%)	1/26 (3.8%)	2/26 (7.7%)
	Poly-K Incidence	5/34.9 (14.3%)	1/16.4 (6.1%)	2/15.3 (13.1%)
	Terminal Incidence	3/16 (18.8%)	0/7 (0.0%)	1/4 (25.0%)
	Time-to-First	569	592	677
	Poly-K P-Value	0.468N	0.351N	0.625N
	Severity Profile	1 3 1 0	0 0 0 1	0 1 0 1
	JT/SW P-Value	0.306N	0.190N	0.332N
	RTE P-Value	0.383N	0.232N	0.383N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 11. Nonneoplasms by Body System for Terminal Sacrifice Females EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Adrenal Cortex * Pigmentation	Simple Incidence	0/50 (0.0%)	0/26 (0.0%)	2/26 (7.7%)
	Poly-K Incidence	0/34.2 (0.0%)	0/15.9 (0.0%)	2/16.1 (12.4%)
	Terminal Incidence	0/16 (0.0%)	0/7 (0.0%)	0/4 (0.0%)
	Time-to-First	----	----	540
	Poly-K P-Value	0.038 *	-----	0.091
	Severity Profile	---	---	0 1 0
	JT/SW P-Value	0.023 *	0.500	0.013 *
	RTE P-Value	0.032 *	0.500	0.032 *
Adrenal Cortex * Vacuolization Cytoplasmic	Simple Incidence	3/50 (6.0%)	3/26 (11.5%)	1/26 (3.8%)
	Poly-K Incidence	3/34.2 (8.8%)	3/17.3 (17.3%)	1/15.7 (6.4%)
	Terminal Incidence	3/16 (18.8%)	0/7 (0.0%)	0/4 (0.0%)
	Time-to-First	725 (T)	497	540
	Poly-K P-Value	0.598	0.329	0.604N
	Severity Profile	1 2 0 0	1 0 0 2	0 1 0 0
	JT/SW P-Value	0.489N	0.813N	0.438N
	RTE P-Value	0.370N	0.164	0.370N
Adrenal Medulla * Hyperplasia	Simple Incidence	8/50 (16.0%)	2/26 (7.7%)	8/26 (30.8%)
	Poly-K Incidence	8/35.8 (22.3%)	2/15.9 (12.6%)	8/17.6 (45.5%)
	Terminal Incidence	4/16 (25.0%)	2/7 (28.6%)	3/4 (75.0%)
	Time-to-First	569	724 (T)	486
	Poly-K P-Value	0.070	0.333N	0.070
	Severity Profile	7 0 1 0	2 0 0 0	4 4 0 0
	JT/SW P-Value	0.103	0.848	0.047 *
	RTE P-Value	0.044 *	0.188N	0.044 *
Parathyroid Gland * Hyperplasia	Simple Incidence	4/50 (8.0%)	3/26 (11.5%)	2/26 (7.7%)
	Poly-K Incidence	4/35.5 (11.3%)	3/16.5 (18.1%)	2/16.0 (12.5%)
	Terminal Incidence	1/16 (6.3%)	1/7 (14.3%)	0/4 (0.0%)
	Time-to-First	477	614	597
	Poly-K P-Value	0.483	0.406	0.630
	Severity Profile	2 2 0 0	1 2 0 0	1 1 0 0
	JT/SW P-Value	0.457	0.300	0.476
	RTE P-Value	0.482N	0.298	0.482N
Pituitary Gland * Angiectasis	Simple Incidence	10/50 (20.0%)	5/26 (19.2%)	17/26 (65.4%)
	Poly-K Incidence	10/37.5 (26.7%)	5/17.1 (29.2%)	17/22.0 (77.4%)
	Terminal Incidence	3/16 (18.8%)	1/7 (14.3%)	3/4 (75.0%)
	Time-to-First	477	614	360
	Poly-K P-Value	<.001 ***	0.552	<.001 ***
	Severity Profile	0 1 1 8	0 0 0 5	0 0 0 17
	JT/SW P-Value	<.001 ***	0.500	<.001 ***
	RTE P-Value	<.001 ***	0.482	<.001 ***

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 11. Nonneoplasms by Body System for Terminal Sacrifice Females EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Pituitary Gland * Cyst,Pars Distalis	Simple Incidence	9/50 (18.0%)	3/26 (11.5%)	2/26 (7.7%)
	Poly-K Incidence	9/37.0 (24.3%)	3/17.6 (17.1%)	2/15.6 (12.8%)
	Terminal Incidence	2/16 (12.5%)	0/7 (0.0%)	1/4 (25.0%)
	Time-to-First	446	484	552
	Poly-K P-Value	0.211N	0.401N	0.289N
Pituitary Gland * Hemorrhage	Simple Incidence	0/50 (0.0%)	0/26 (0.0%)	3/26 (11.5%)
	Poly-K Incidence	0/34.2 (0.0%)	0/15.9 (0.0%)	3/16.3 (18.4%)
	Terminal Incidence	0/16 (0.0%)	0/7 (0.0%)	1/4 (25.0%)
	Time-to-First	----	----	529
	Poly-K P-Value	0.008 **	-----	0.023 *
	Severity Profile	---	---	0 0 0 3
	JT/SW P-Value	0.007 **	0.500	0.003 **
	RTE P-Value	0.007 **	0.500	0.007 **
Pituitary Gland * Hyperplasia,Pars Distalis	Simple Incidence	27/50 (54.0%)	16/26 (61.5%)	6/26 (23.1%)
	Poly-K Incidence	27/43.6 (61.9%)	16/23.6 (67.8%)	6/16.9 (35.5%)
	Terminal Incidence	9/16 (56.3%)	3/7 (42.9%)	2/4 (50.0%)
	Time-to-First	431	443	552
	Poly-K P-Value	0.114N	0.411	0.055N
	Severity Profile	0 3 12 12	0 3 5 8	0 1 2 3
	JT/SW P-Value	0.028N*	0.721N	0.010N**
	RTE P-Value	0.010N**	0.268	0.010N**
Thyroid Gland * Hyperplasia,C-Cell	Simple Incidence	22/50 (44.0%)	7/26 (26.9%)	9/25 (36.0%)
	Poly-K Incidence	22/40.7 (54.0%)	7/18.7 (37.3%)	9/18.1 (49.6%)
	Terminal Incidence	8/16 (50.0%)	2/7 (28.6%)	2/4 (50.0%)
	Time-to-First	450	505	488
	Poly-K P-Value	0.331N	0.172N	0.487N
	Severity Profile	11 9 2 0	2 5 0 0	6 2 0 1
	JT/SW P-Value	0.146N	0.105N	0.179N
	RTE P-Value	0.213N	0.094N	0.213N
Thyroid Gland * Hyperplasia,Follicular Cell	Simple Incidence	1/50 (2.0%)	4/26 (15.4%)	0/25 (0.0%)
	Poly-K Incidence	1/34.2 (2.9%)	4/17.9 (22.3%)	0/14.7 (0.0%)
	Terminal Incidence	1/16 (6.3%)	0/7 (0.0%)	0/4 (0.0%)
	Time-to-First	726 (T)	443	----
	Poly-K P-Value	0.457	0.034 *	0.664N
	Severity Profile	0 1 0 0	0 1 3 0	---
	JT/SW P-Value	0.329	0.012 * ¹	0.158
	RTE P-Value	0.354N	0.007 **	0.354N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 11. Nonneoplasms by Body System for Terminal Sacrifice Females EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Thyroid Gland * Ultimobranchial Cyst	Simple Incidence	8/50 (16.0%)	5/26 (19.2%)	8/25 (32.0%)
	Poly-K Incidence	8/36.4 (22.0%)	5/17.5 (28.6%)	8/17.4 (45.9%)
	Terminal Incidence	4/16 (25.0%)	2/7 (28.6%)	1/4 (25.0%)
	Time-to-First	431	485	360
	Poly-K P-Value	0.048 *	0.424	0.062
Genital System				
Ovary * Atrophy	Simple Incidence	47/50 (94.0%)	25/26 (96.2%)	26/26 (100.0%)
	Poly-K Incidence	47/48.7 (96.5%)	25/26.0 (96.2%)	26/26.0 (100.0%)
	Terminal Incidence	16/16 (100.0%)	6/7 (85.7%)	4/4 (100.0%)
	Time-to-First	431	443	360
	Poly-K P-Value	0.315	0.736N	0.430
	Severity Profile	0 24 15 8	0 12 7 6	0 1 1 24
	JT/SW P-Value	<.001 ***	0.282	<.001 ***
RTE P-Value	<.001 ***	0.243	<.001 ***	
Ovary * Cyst	Simple Incidence	4/50 (8.0%)	5/26 (19.2%)	5/26 (19.2%)
	Poly-K Incidence	4/34.2 (11.7%)	5/16.4 (30.4%)	5/15.8 (31.6%)
	Terminal Incidence	3/16 (18.8%)	4/7 (57.1%)	2/4 (50.0%)
	Time-to-First	720	579	597
	Poly-K P-Value	0.049 *	0.104	0.093
Ovary * Cyst,Bursa	Simple Incidence	0/50 (0.0%)	1/26 (3.8%)	2/26 (7.7%)
	Poly-K Incidence	0/34.2 (0.0%)	1/16.1 (6.2%)	2/15.9 (12.6%)
	Terminal Incidence	0/16 (0.0%)	0/7 (0.0%)	0/4 (0.0%)
	Time-to-First	----	672	582
	Poly-K P-Value	0.049 *	0.351	0.090
Ovary * Cyst,Follicle	Simple Incidence	3/50 (6.0%)	0/26 (0.0%)	3/26 (11.5%)
	Poly-K Incidence	3/35.7 (8.4%)	0/15.9 (0.0%)	3/16.1 (18.6%)
	Terminal Incidence	0/16 (0.0%)	0/7 (0.0%)	1/4 (25.0%)
	Time-to-First	538	----	540
	Poly-K P-Value	0.276	0.297N	0.281
Ovary * Hyperplasia,Sertoliform	Simple Incidence	4/50 (8.0%)	3/26 (11.5%)	3/26 (11.5%)
	Poly-K Incidence	4/34.6 (11.6%)	3/16.9 (17.8%)	3/15.7 (19.1%)
	Terminal Incidence	2/16 (12.5%)	1/7 (14.3%)	1/4 (25.0%)
	Time-to-First	667	497	610
	Poly-K P-Value	0.294	0.429	0.392
	Severity Profile	4 0 0 0	1 1 1 0	2 0 0 1
	JT/SW P-Value	0.265	0.278	0.346
RTE P-Value	0.298	0.287	0.298	

RR9: CLARITY-BPA Core Study

Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 11. Nonneoplasms by Body System for Terminal Sacrifice Females EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Uterus * Atrophy	Simple Incidence	7/50 (14.0%)	1/26 (3.8%)	9/26 (34.6%)
	Poly-K Incidence	7/35.6 (19.7%)	1/15.9 (6.3%)	9/19.7 (45.6%)
	Terminal Incidence	1/16 (6.3%)	1/7 (14.3%)	1/4 (25.0%)
	Time-to-First	620	728 (T)	360
	Poly-K P-Value	0.026 *	0.213N	0.033 *
	Severity Profile	0 0 7 0	0 0 1 0	0 0 5 4
	JT/SW P-Value	0.034 *	0.913	0.008 **
	RTE P-Value	0.007 **	0.137N	0.007 **
Uterus * Cyst,Endometrium	Simple Incidence	0/50 (0.0%)	0/26 (0.0%)	2/26 (7.7%)
	Poly-K Incidence	0/34.2 (0.0%)	0/15.9 (0.0%)	2/15.8 (12.7%)
	Terminal Incidence	0/16 (0.0%)	0/7 (0.0%)	0/4 (0.0%)
	Time-to-First	----	----	529
	Poly-K P-Value	0.038 *	-----	0.089
Uterus * Dilatation,Lumen	Simple Incidence	2/50 (4.0%)	2/26 (7.7%)	3/26 (11.5%)
	Poly-K Incidence	2/35.6 (5.6%)	2/16.9 (11.8%)	3/16.0 (18.8%)
	Terminal Incidence	0/16 (0.0%)	0/7 (0.0%)	1/4 (25.0%)
	Time-to-First	446	485	552
	Poly-K P-Value	0.116	0.409	0.170
	Severity Profile	0 0 0 2	0 0 0 2	0 0 0 3
	JT/SW P-Value	0.108	0.248	0.130
	RTE P-Value	0.118	0.275	0.118
Uterus * Hyperplasia,Cystic,Endometrium	Simple Incidence	30/50 (60.0%)	14/26 (53.8%)	14/26 (53.8%)
	Poly-K Incidence	30/41.9 (71.6%)	14/21.8 (64.3%)	14/20.2 (69.2%)
	Terminal Incidence	13/16 (81.3%)	2/7 (28.6%)	2/4 (50.0%)
	Time-to-First	431	460	462
	Poly-K P-Value	0.434N	0.366N	0.547N
	Severity Profile	4 18 5 3	1 7 4 2	1 8 2 3
	JT/SW P-Value	0.463N	0.491N	0.539N
	RTE P-Value	0.460N	0.488N	0.460N
Uterus * Hyperplasia,Endometrial Glands	Simple Incidence	1/50 (2.0%)	2/26 (7.7%)	1/26 (3.8%)
	Poly-K Incidence	1/34.9 (2.9%)	2/16.3 (12.3%)	1/15.5 (6.5%)
	Terminal Incidence	0/16 (0.0%)	1/7 (14.3%)	0/4 (0.0%)
	Time-to-First	477	614	616
	Poly-K P-Value	0.333	0.247	0.569
	Severity Profile	0 1 0 0	0 2 0 0	0 1 0 0
	JT/SW P-Value	0.250	0.115	0.254
	RTE P-Value	0.349	0.124	0.349

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 11. Nonneoplasms by Body System for Terminal Sacrifice Females EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Uterus * Hyperplasia,Endometrium	Simple Incidence	10/50 (20.0%)	10/26 (38.5%)	2/26 (7.7%)
	Poly-K Incidence	10/39.1 (25.6%)	10/19.4 (51.5%)	2/16.2 (12.3%)
	Terminal Incidence	2/16 (12.5%)	4/7 (57.1%)	0/4 (0.0%)
	Time-to-First	488	443	488
	Poly-K P-Value	0.491N	0.040 *	0.240N
	Severity Profile	2 8 0 0	3 6 0 1	1 1 0 0
	JT/SW P-Value	0.268N	0.955N	0.119N
	RTE P-Value	0.094N	0.036 *	0.094N
Uterus * Metaplasia,Squamous	Simple Incidence	2/50 (4.0%)	2/26 (7.7%)	4/26 (15.4%)
	Poly-K Incidence	2/35.7 (5.6%)	2/16.1 (12.4%)	4/16.9 (23.6%)
	Terminal Incidence	0/16 (0.0%)	1/7 (14.3%)	1/4 (25.0%)
	Time-to-First	431	672	462
	Poly-K P-Value	0.046 *	0.390	0.071
	Severity Profile	1 1 0 0	0 2 0 0	3 0 1 0
	JT/SW P-Value	0.049 *	0.240	0.050
	RTE P-Value	0.055	0.273	0.055
Vagina * Atrophy	Simple Incidence	1/49 (2.0%)	0/26 (0.0%)	3/26 (11.5%)
	Poly-K Incidence	1/33.9 (2.9%)	0/15.9 (0.0%)	3/16.2 (18.6%)
	Terminal Incidence	0/16 (0.0%)	0/7 (0.0%)	1/4 (25.0%)
	Time-to-First	672	----	540
	Poly-K P-Value	0.055	0.648N	0.089
	Severity Profile	0 0 1 0	---	0 1 1 1
	JT/SW P-Value	0.051	0.767	0.026 *
	RTE P-Value	0.035 *	0.332N	0.035 *
Vagina * Degeneration,Epithelium	Simple Incidence	1/49 (2.0%)	1/26 (3.8%)	2/26 (7.7%)
	Poly-K Incidence	1/34.2 (2.9%)	1/15.9 (6.3%)	2/16.6 (12.1%)
	Terminal Incidence	0/16 (0.0%)	1/7 (14.3%)	0/4 (0.0%)
	Time-to-First	564	728 (T)	360
	Poly-K P-Value	0.169	0.580	0.257
	Severity Profile	0 0 1 0	0 0 0 1	0 1 1 0
	JT/SW P-Value	0.131	0.316	0.145
	RTE P-Value	0.146	0.344	0.146
Vagina * Hyperplasia,Epithelium	Simple Incidence	4/49 (8.2%)	5/26 (19.2%)	2/26 (7.7%)
	Poly-K Incidence	4/35.2 (11.4%)	5/18.6 (26.9%)	2/15.8 (12.6%)
	Terminal Incidence	2/16 (12.5%)	0/7 (0.0%)	1/4 (25.0%)
	Time-to-First	431	484	462
	Poly-K P-Value	0.386	0.139	0.629
	Severity Profile	0 1 2 1	0 1 2 2	0 1 1 0
	JT/SW P-Value	0.380	0.078	0.291
	RTE P-Value	0.459N	0.076	0.459N

RR9: CLARITY-BPA Core Study

Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 11. Nonneoplasms by Body System for Terminal Sacrifice Females EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Vagina * Infiltration Cellular,Polymorphonuclear	Simple Incidence	7/49 (14.3%)	3/26 (11.5%)	2/26 (7.7%)
	Poly-K Incidence	7/36.3 (19.3%)	3/16.6 (18.1%)	2/16.3 (12.3%)
	Terminal Incidence	2/16 (12.5%)	1/7 (14.3%)	0/4 (0.0%)
	Time-to-First	495	614	486
	Poly-K P-Value	0.352N	0.606N	0.411N
	Severity Profile	0 2 2 3	0 2 1 0	0 1 0 1
	JT/SW P-Value	0.190N	0.332N	0.233N
	RTE P-Value	0.197N	0.331N	0.197N
Vagina * Mucification,Epithelium	Simple Incidence	46/49 (93.9%)	21/26 (80.8%)	23/26 (88.5%)
	Poly-K Incidence	46/47.2 (97.4%)	21/24.0 (87.4%)	23/24.8 (92.8%)
	Terminal Incidence	16/16 (100.0%)	6/7 (85.7%)	3/4 (75.0%)
	Time-to-First	450	443	360
	Poly-K P-Value	0.188N	0.080N	0.356N
	Severity Profile	0 13 12 21	0 4 5 12	0 6 8 9
	JT/SW P-Value	0.275N	0.409N	0.321N
	RTE P-Value	0.271N	0.408N	0.271N
Hematopoietic System				
Bone Marrow * Hyperplasia,Myeloid Cell	Simple Incidence	0/50 (0.0%)	0/26 (0.0%)	2/26 (7.7%)
	Poly-K Incidence	0/34.2 (0.0%)	0/15.9 (0.0%)	2/15.7 (12.8%)
	Terminal Incidence	0/16 (0.0%)	0/7 (0.0%)	1/4 (25.0%)
	Time-to-First	----	----	540
	Poly-K P-Value	0.038 *	-----	0.088
	Severity Profile	---	---	0 1 1 0
	JT/SW P-Value	0.023 *	0.500	0.013 *
	RTE P-Value	0.032 *	0.500	0.032 *
Spleen * Hematopoietic Cell Proliferation	Simple Incidence	28/50 (56.0%)	15/26 (57.7%)	10/26 (38.5%)
	Poly-K Incidence	28/44.0 (63.7%)	15/20.7 (72.4%)	10/19.1 (52.5%)
	Terminal Incidence	8/16 (50.0%)	5/7 (71.4%)	1/4 (25.0%)
	Time-to-First	431	485	488
	Poly-K P-Value	0.328N	0.333	0.283N
	Severity Profile	5 12 6 5	5 5 4 1	1 6 2 1
	JT/SW P-Value	0.089N	0.382N	0.089N
	RTE P-Value	0.077N	0.392N	0.077N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 11. Nonneoplasms by Body System for Terminal Sacrifice Females EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Spleen * Pigmentation	Simple Incidence	32/50 (64.0%)	19/26 (73.1%)	26/26 (100.0%)
	Poly-K Incidence	32/44.2 (72.5%)	19/24.4 (77.9%)	26/26.0 (100.0%)
	Terminal Incidence	11/16 (68.8%)	4/7 (57.1%)	4/4 (100.0%)
	Time-to-First	431	443	360
	Poly-K P-Value	0.001 **	0.414	<.001 ***
	Severity Profile	7 13 6 6	4 3 7 5	1 4 8 13
	JT/SW P-Value	<.001 ***	0.097	<.001 ***
	RTE P-Value	<.001 ***	0.068	<.001 ***
Thymus * Atrophy	Simple Incidence	47/50 (94.0%)	26/26 (100.0%)	25/26 (96.2%)
	Poly-K Incidence	47/49.3 (95.4%)	26/26.0 (100.0%)	25/25.4 (98.4%)
	Terminal Incidence	16/16 (100.0%)	7/7 (100.0%)	4/4 (100.0%)
	Time-to-First	431	443	360
	Poly-K P-Value	0.260	0.323	0.493
	Severity Profile	0 2 4 41	0 0 5 21	0 1 7 17
	JT/SW P-Value	0.103N	0.529N	0.085N
	RTE P-Value	0.075N	0.456	0.075N
Integumentary System				
Mammary Gland * Atypical Focus	Simple Incidence	2/50 (4.0%)	2/26 (7.7%)	3/26 (11.5%)
	Poly-K Incidence	2/34.4 (5.8%)	2/16.1 (12.4%)	3/16.2 (18.6%)
	Terminal Incidence	1/16 (6.3%)	1/7 (14.3%)	0/4 (0.0%)
	Time-to-First	672	672	540
	Poly-K P-Value	0.123	0.404	0.183
	Severity Profile	0 2 0 0	1 1 0 0	2 1 0 0
	JT/SW P-Value	0.118	0.258	0.142
	RTE P-Value	0.139	0.284	0.139
Mammary Gland * Dilatation,Alveolus	Simple Incidence	9/50 (18.0%)	5/26 (19.2%)	22/26 (84.6%)
	Poly-K Incidence	9/36.0 (25.0%)	5/18.8 (26.6%)	22/24.1 (91.4%)
	Terminal Incidence	5/16 (31.3%)	0/7 (0.0%)	4/4 (100.0%)
	Time-to-First	477	484	360
	Poly-K P-Value	<.001 ***	0.579	<.001 ***
	Severity Profile	1 7 1 0	0 5 0 0	0 18 4 0
	JT/SW P-Value	<.001 ***	0.448	<.001 ***
	RTE P-Value	<.001 ***	0.453	<.001 ***

RR9: CLARITY-BPA Core Study

Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 11. Nonneoplasms by Body System for Terminal Sacrifice Females EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Mammary Gland * Dilatation,Duct	Simple Incidence	15/50 (30.0%)	6/26 (23.1%)	21/26 (80.8%)
	Poly-K Incidence	15/38.1 (39.4%)	6/19.0 (31.6%)	21/24.2 (86.9%)
	Terminal Incidence	7/16 (43.8%)	0/7 (0.0%)	3/4 (75.0%)
	Time-to-First	477	484	360
	Poly-K P-Value	<.001 ***	0.387N	<.001 ***
	Severity Profile	0 10 5 0	0 3 3 0	0 10 7 4
	JT/SW P-Value	<.001 ***	0.700	<.001 ***
	RTE P-Value	<.001 ***	0.321N	<.001 ***
Mammary Gland * Galactocele	Simple Incidence	0/50 (0.0%)	0/26 (0.0%)	2/26 (7.7%)
	Poly-K Incidence	0/34.2 (0.0%)	0/15.9 (0.0%)	2/16.1 (12.4%)
	Terminal Incidence	0/16 (0.0%)	0/7 (0.0%)	0/4 (0.0%)
	Time-to-First	----	----	488
	Poly-K P-Value	0.038 *	-----	0.091
	Mammary Gland * Hyperplasia,Lobular	Simple Incidence	43/50 (86.0%)	24/26 (92.3%)
Poly-K Incidence		43/45.4 (94.7%)	24/24.5 (98.1%)	23/25.1 (91.5%)
Terminal Incidence		16/16 (100.0%)	7/7 (100.0%)	4/4 (100.0%)
Time-to-First		477	484	360
Poly-K P-Value		0.416N	0.468	0.495N
Severity Profile		1 8 13 21	1 8 4 11	1 10 4 8
JT/SW P-Value		0.135N	0.431N	0.134N
RTE P-Value		0.118N	0.430N	0.118N
Nervous System				
Brain, Brain Stem * Compression	Simple Incidence	14/50 (28.0%)	6/26 (23.1%)	19/26 (73.1%)
	Poly-K Incidence	14/38.6 (36.2%)	6/17.9 (33.5%)	19/23.7 (80.3%)
	Terminal Incidence	3/16 (18.8%)	2/7 (28.6%)	2/4 (50.0%)
	Time-to-First	477	484	360
	Poly-K P-Value	<.001 ***	0.539N	<.001 ***
	Severity Profile	1 3 4 6	2 1 2 1	4 6 3 6
	JT/SW P-Value	0.002 **	0.749	<.001 ***
	RTE P-Value	<.001 ***	0.229N	<.001 ***
Brain, Brain Stem * Hemorrhage	Simple Incidence	1/50 (2.0%)	1/26 (3.8%)	5/26 (19.2%)
	Poly-K Incidence	1/34.6 (2.9%)	1/16.6 (6.0%)	5/18.0 (27.8%)
	Terminal Incidence	0/16 (0.0%)	0/7 (0.0%)	0/4 (0.0%)
	Time-to-First	615	484	360
	Poly-K P-Value	0.005 **	0.589	0.009 **
	Severity Profile	0 1 0 0	0 1 0 0	0 4 1 0
	JT/SW P-Value	0.006 **	0.318	0.003 **
	RTE P-Value	0.004 **	0.379	0.004 **

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 11. Nonneoplasms by Body System for Terminal Sacrifice Females EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Brain, Cerebrum * Dilatation, Ventricle	Simple Incidence	7/50 (14.0%)	2/26 (7.7%)	8/26 (30.8%)
	Poly-K Incidence	7/36.0 (19.5%)	2/17.0 (11.7%)	8/19.2 (41.7%)
	Terminal Incidence	1/16 (6.3%)	0/7 (0.0%)	0/4 (0.0%)
	Time-to-First	495	484	360
	Poly-K P-Value	0.058	0.380N	0.065
	Severity Profile	4 3 0 0	2 0 0 0	5 3 0 0
	JT/SW P-Value	0.080	0.805	0.038 *
	RTE P-Value	0.035 *	0.219N	0.035 *
Respiratory System				
Lung * Hyperplasia, Alveolar Epithelium	Simple Incidence	4/38 (10.5%)	1/21 (4.8%)	0/22 (0.0%)
	Poly-K Incidence	4/22.8 (17.5%)	1/10.9 (9.2%)	0/11.1 (0.0%)
	Terminal Incidence	2/4 (50.0%)	1/2 (50.0%)	
	Time-to-First	625	724 (T)	----
	Poly-K P-Value	0.108N	0.452N	0.182N
	Severity Profile	2 2 0 0	0 1 0 0	---
	JT/SW P-Value	0.052N	0.235N	0.062N
	RTE P-Value	0.064N	0.201N	0.064N
Lung * Infiltration Cellular, Histiocyte	Simple Incidence	8/38 (21.1%)	4/21 (19.0%)	4/22 (18.2%)
	Poly-K Incidence	8/24.4 (32.8%)	4/11.8 (33.8%)	4/13.0 (30.8%)
	Terminal Incidence	3/4 (75.0%)	2/2 (100.0%)	
	Time-to-First	488	517	540
	Poly-K P-Value	0.533N	0.628	0.599N
	Severity Profile	1 5 2 0	2 0 1 1	1 1 0 2
	JT/SW P-Value	0.419N	0.428N	0.504N
	RTE P-Value	0.430N	0.430N	0.430N
Nose * Accumulation, Hyaline Droplet, Olfactory Epithelium	Simple Incidence	8/34 (23.5%)	3/19 (15.8%)	7/22 (31.8%)
	Poly-K Incidence	8/20.5 (39.0%)	3/10.5 (28.5%)	7/14.0 (49.8%)
	Time-to-First	569	443	462
	Poly-K P-Value	0.331	0.422N	0.377
	Severity Profile	1 4 3 0	1 2 0 0	2 1 1 3
	JT/SW P-Value	0.277	0.788	0.248
	RTE P-Value	0.209	0.235N	0.209
	Nose * Accumulation, Hyaline Droplet, Respiratory Epithelium	Simple Incidence	2/34 (5.9%)	0/19 (0.0%)
Poly-K Incidence		2/18.6 (10.7%)	0/8.9 (0.0%)	3/12.3 (24.5%)
Time-to-First		667	----	527
Poly-K P-Value		0.222	0.410N	0.298
Severity Profile		0 2 0 0	---	1 2 0 0
JT/SW P-Value		0.196	0.857	0.162
RTE P-Value		0.151	0.203N	0.151

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 11. Nonneoplasms by Body System for Terminal Sacrifice Females EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Nose * Hyperplasia,Goblet Cell,Respiratory Epithelium	Simple Incidence	1/34 (2.9%)	0/19 (0.0%)	2/22 (9.1%)
	Poly-K Incidence	1/18.8 (5.3%)	0/8.9 (0.0%)	2/11.6 (17.3%)
	Time-to-First	538	----	597
	Poly-K P-Value	0.226	0.646N	0.327
	Severity Profile	0 1 0 0	---	0 2 0 0
	JT/SW P-Value	0.172	0.773	0.152
	RTE P-Value	0.144	0.302N	0.144
Urinary System				
Kidney * Casts Protein	Simple Incidence	8/50 (16.0%)	3/26 (11.5%)	2/26 (7.7%)
	Poly-K Incidence	8/35.9 (22.3%)	3/16.9 (17.7%)	2/15.6 (12.9%)
	Terminal Incidence	5/16 (31.3%)	1/7 (14.3%)	1/4 (25.0%)
	Time-to-First	450	460	589
	Poly-K P-Value	0.275N	0.493N	0.346N
	Severity Profile	8 0 0 0	3 0 0 0	2 0 0 0
	JT/SW P-Value	0.148N	0.301N	0.182N
RTE P-Value	0.157N	0.292N	0.157N	
Kidney * Cyst,Cortex	Simple Incidence	5/50 (10.0%)	7/26 (26.9%)	2/26 (7.7%)
	Poly-K Incidence	5/36.2 (13.8%)	7/18.9 (37.0%)	2/16.2 (12.4%)
	Terminal Incidence	1/16 (6.3%)	2/7 (28.6%)	0/4 (0.0%)
	Time-to-First	488	443	488
	Poly-K P-Value	0.397	0.045 *	0.613N
Kidney * Cyst,Renal Tubule	Simple Incidence	9/50 (18.0%)	5/26 (19.2%)	6/26 (23.1%)
	Poly-K Incidence	9/36.2 (24.8%)	5/18.3 (27.3%)	6/17.6 (34.1%)
	Terminal Incidence	5/16 (31.3%)	0/7 (0.0%)	1/4 (25.0%)
	Time-to-First	446	485	527
	Poly-K P-Value	0.299	0.554	0.349
Kidney * Hyperplasia,Transitional Epithelium	Simple Incidence	12/50 (24.0%)	5/26 (19.2%)	9/26 (34.6%)
	Poly-K Incidence	12/35.4 (33.9%)	5/17.3 (28.9%)	9/18.5 (48.7%)
	Terminal Incidence	7/16 (43.8%)	3/7 (42.9%)	3/4 (75.0%)
	Time-to-First	569	484	360
	Poly-K P-Value	0.200	0.481N	0.210
	Severity Profile	8 4 0 0	3 2 0 0	5 4 0 0
	JT/SW P-Value	0.207	0.669	0.169
RTE P-Value	0.150	0.342N	0.150	

RR9: CLARITY-BPA Core Study

Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 11. Nonneoplasms by Body System for Terminal Sacrifice Females EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Kidney * Mineralization	Simple Incidence	30/50 (60.0%)	10/26 (38.5%)	17/26 (65.4%)
	Poly-K Incidence	30/42.9 (69.9%)	10/20.7 (48.4%)	17/22.0 (77.2%)
	Terminal Incidence	10/16 (62.5%)	2/7 (28.6%)	3/4 (75.0%)
	Time-to-First	446	443	360
	Poly-K P-Value	0.445	0.068N	0.359
	Severity Profile	21 8 1 0	4 5 1 0	10 7 0 0
	JT/SW P-Value	0.399	0.866	0.305
	RTE P-Value	0.255	0.144N	0.255
Kidney * Nephropathy	Simple Incidence	19/50 (38.0%)	14/26 (53.8%)	15/26 (57.7%)
	Poly-K Incidence	19/39.9 (47.6%)	14/21.0 (66.7%)	15/21.6 (69.6%)
	Terminal Incidence	6/16 (37.5%)	4/7 (57.1%)	2/4 (50.0%)
	Time-to-First	488	485	360
	Poly-K P-Value	0.037 *	0.109	0.067
	Severity Profile	18 0 1 0	10 3 1 0	6 5 3 1
	JT/SW P-Value	0.004 **	0.049 *	0.006 **
	RTE P-Value	0.006 **	0.062	0.006 **

P-values for dose trend are presented in the “Control” column.

N indicates a negative trend or negative treatment comparison to control with corresponding lower-tail p-values.

¹Nonsignificant SW test due to the assumption of monotonicity.

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 12. Nonneoplasms by Body System for Terminal Sacrifice Males EE2 Continuous Dose Arm				
System and Nonneoplasm		Treatment (ug/kg)		
Lesion	Statistic	Control	0.05	0.50
Alimentary System				
Liver * Angiectasis	Simple Incidence	1/50 (2.0%)	2/26 (7.7%)	2/25 (8.0%)
	Poly-K Incidence	1/33.7 (3.0%)	2/17.9 (11.1%)	2/19.9 (10.1%)
	Terminal Incidence	1/15 (6.7%)	1/9 (11.1%)	1/12 (8.3%)
	Time-to-First	727 (T)	638	559
	Poly-K P-Value	0.222	0.282	0.313
	Severity Profile	0 1 0 0	0 2 0 0	0 1 0 1
	JT/SW P-Value	0.095	0.115	0.149
	RTE P-Value	0.117	0.154	0.117
Liver * Basophilic Focus	Simple Incidence	5/50 (10.0%)	3/26 (11.5%)	0/25 (0.0%)
	Poly-K Incidence	5/34.3 (14.6%)	3/17.8 (16.9%)	0/19.3 (0.0%)
	Terminal Incidence	3/15 (20.0%)	2/9 (22.2%)	0/12 (0.0%)
	Time-to-First	622	679	----
	Poly-K P-Value	0.093N	0.575	0.094N
Liver * Clear Cell Focus	Simple Incidence	11/50 (22.0%)	7/26 (26.9%)	9/25 (36.0%)
	Poly-K Incidence	11/35.7 (30.8%)	7/19.2 (36.4%)	9/20.9 (43.1%)
	Terminal Incidence	6/15 (40.0%)	2/9 (22.2%)	5/12 (41.7%)
	Time-to-First	566	543	413
	Poly-K P-Value	0.208	0.450	0.250
Liver * Degeneration,Cystic	Simple Incidence	21/50 (42.0%)	10/26 (38.5%)	10/25 (40.0%)
	Poly-K Incidence	21/38.2 (55.0%)	10/19.6 (51.0%)	10/20.4 (49.0%)
	Terminal Incidence	9/15 (60.0%)	4/9 (44.4%)	5/12 (41.7%)
	Time-to-First	425	551	590
	Poly-K P-Value	0.371N	0.496N	0.431N
	Severity Profile	14 6 1 0	4 6 0 0	6 4 0 0
	JT/SW P-Value	0.470N	0.510N	0.541N
	RTE P-Value	0.462N	0.490	0.462N
Liver * Fatty Change	Simple Incidence	4/50 (8.0%)	0/26 (0.0%)	1/25 (4.0%)
	Poly-K Incidence	4/35.1 (11.4%)	0/17.6 (0.0%)	1/19.9 (5.0%)
	Terminal Incidence	2/15 (13.3%)	0/9 (0.0%)	0/12 (0.0%)
	Time-to-First	225	----	559
	Poly-K P-Value	0.228N	0.177N	0.380N
	Severity Profile	0 1 1 2	---	0 0 0 1
	JT/SW P-Value	0.142N	0.071N	0.158N
	RTE P-Value	0.234N	0.080N	0.234N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 12. Nonneoplasms by Body System for Terminal Sacrifice Males EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Liver * Fibrosis,Biliary Tract	Simple Incidence	13/50 (26.0%)	7/26 (26.9%)	8/25 (32.0%)
	Poly-K Incidence	13/35.9 (36.2%)	7/18.8 (37.3%)	8/19.7 (40.6%)
	Terminal Incidence	7/15 (46.7%)	3/9 (33.3%)	6/12 (50.0%)
	Time-to-First	566	577	639
	Poly-K P-Value	0.433	0.589	0.487
	Severity Profile	9 4 0 0	6 1 0 0	7 1 0 0
	JT/SW P-Value	0.364	0.509	0.406
	RTE P-Value	0.343	0.490N	0.343
Liver * Hepatodiaphragmatic Nodule	Simple Incidence	6/50 (12.0%)	3/26 (11.5%)	1/25 (4.0%)
	Poly-K Incidence	6/34.6 (17.3%)	3/17.8 (16.9%)	1/19.5 (5.1%)
	Terminal Incidence	3/15 (20.0%)	2/9 (22.2%)	0/12 (0.0%)
	Time-to-First	603	679	673
	Poly-K P-Value	0.158N	0.635N	0.188N
Liver * Hyperplasia,Bile Duct	Simple Incidence	16/50 (32.0%)	10/26 (38.5%)	8/25 (32.0%)
	Poly-K Incidence	16/38.5 (41.5%)	10/20.8 (48.0%)	8/20.3 (39.4%)
	Terminal Incidence	6/15 (40.0%)	4/9 (44.4%)	4/12 (33.3%)
	Time-to-First	284	459	551
	Poly-K P-Value	0.530N	0.415	0.550N
	Severity Profile	7 8 1 0	5 3 2 0	5 1 2 0
	JT/SW P-Value	0.454	0.286	0.471
	RTE P-Value	0.476N	0.287	0.476N
Liver * Hyperplasia,Oval Cell	Simple Incidence	4/50 (8.0%)	1/26 (3.8%)	1/25 (4.0%)
	Poly-K Incidence	4/34.0 (11.8%)	1/17.6 (5.7%)	1/19.3 (5.2%)
	Terminal Incidence	2/15 (13.3%)	1/9 (11.1%)	1/12 (8.3%)
	Time-to-First	647	725 (T)	725 (T)
	Poly-K P-Value	0.270N	0.420N	0.379N
	Severity Profile	3 1 0 0	1 0 0 0	0 0 1 0
	JT/SW P-Value	0.220N	0.242N	0.297N
	RTE P-Value	0.262N	0.236N	0.262N
Liver * Infiltration Cellular,Mononuclear Cell	Simple Incidence	35/50 (70.0%)	22/26 (84.6%)	20/25 (80.0%)
	Poly-K Incidence	35/42.3 (82.6%)	22/23.5 (93.6%)	20/23.1 (86.8%)
	Terminal Incidence	14/15 (93.3%)	9/9 (100.0%)	10/12 (83.3%)
	Time-to-First	284	369	413
	Poly-K P-Value	0.311	0.150	0.464
	Severity Profile	21 14 0 0	16 6 0 0	12 8 0 0
	JT/SW P-Value	0.200	0.293	0.259
	RTE P-Value	0.219	0.301	0.219

RR9: CLARITY-BPA Core Study

Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 12. Nonneoplasms by Body System for Terminal Sacrifice Males EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Liver * Tension Lipidosis	Simple Incidence	3/50 (6.0%)	1/26 (3.8%)	2/25 (8.0%)
	Poly-K Incidence	3/33.8 (8.9%)	1/17.6 (5.7%)	2/19.4 (10.3%)
	Terminal Incidence	1/15 (6.7%)	1/9 (11.1%)	1/12 (8.3%)
	Time-to-First	709	725 (T)	710
	Poly-K P-Value	0.557	0.557N	0.625
	Severity Profile	0 0 1 2	0 0 1 0	0 1 1 0
	JT/SW P-Value	0.450	0.664	0.462
	RTE P-Value	0.391	0.344N	0.391
Liver * Vacuolization Cytoplasmic	Simple Incidence	12/50 (24.0%)	11/26 (42.3%)	12/25 (48.0%)
	Poly-K Incidence	12/37.3 (32.2%)	11/19.3 (57.0%)	12/20.5 (58.5%)
	Terminal Incidence	4/15 (26.7%)	7/9 (77.8%)	8/12 (66.7%)
	Time-to-First	520	551	462
	Poly-K P-Value	0.020 *	0.055	0.037 *
	Severity Profile	6 3 3 0	3 8 0 0	4 7 1 0
	JT/SW P-Value	0.013 *	0.050 *	0.024 *
	RTE P-Value	0.025 *	0.055	0.025 *
Pancreas * Degeneration,Acinus	Simple Incidence	42/50 (84.0%)	20/26 (76.9%)	21/25 (84.0%)
	Poly-K Incidence	42/46.5 (90.2%)	20/22.4 (89.1%)	21/23.3 (90.2%)
	Terminal Incidence	14/15 (93.3%)	9/9 (100.0%)	11/12 (91.7%)
	Time-to-First	225	369	413
	Poly-K P-Value	0.586N	0.627N	0.685N
	Severity Profile	7 9 13 13	3 6 7 4	2 5 7 7
	JT/SW P-Value	0.495	0.835	0.434
	RTE P-Value	0.366	0.167N	0.366
Pancreas * Infiltration Cellular,Lymphocyte	Simple Incidence	36/50 (72.0%)	18/26 (69.2%)	16/25 (64.0%)
	Poly-K Incidence	36/42.7 (84.4%)	18/21.7 (82.8%)	16/22.3 (71.7%)
	Terminal Incidence	13/15 (86.7%)	9/9 (100.0%)	9/12 (75.0%)
	Time-to-First	284	369	413
	Poly-K P-Value	0.125N	0.588N	0.160N
	Severity Profile	10 17 9 0	4 13 1 0	6 8 2 0
	JT/SW P-Value	0.118N	0.283N	0.143N
	RTE P-Value	0.121N	0.293N	0.121N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 12. Nonneoplasms by Body System for Terminal Sacrifice Males EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Pancreas * Inflammation,Chronic Active	Simple Incidence	1/50 (2.0%)	0/26 (0.0%)	2/25 (8.0%)
	Poly-K Incidence	1/33.7 (3.0%)	0/17.6 (0.0%)	2/19.5 (10.2%)
	Terminal Incidence	1/15 (6.7%)	0/9 (0.0%)	1/12 (8.3%)
	Time-to-First	727 (T)	---	673
	Poly-K P-Value	0.210	0.630N	0.308
	Severity Profile	0 1 0 0	---	0 2 0 0
	JT/SW P-Value	0.136	0.765	0.089
	RTE P-Value	0.105	0.313N	0.105
Pancreas * Lipomatosis	Simple Incidence	7/50 (14.0%)	7/26 (26.9%)	7/25 (28.0%)
	Poly-K Incidence	7/34.4 (20.3%)	7/18.3 (38.2%)	7/19.3 (36.2%)
	Terminal Incidence	5/15 (33.3%)	5/9 (55.6%)	6/12 (50.0%)
	Time-to-First	526	561	725 (T)
	Poly-K P-Value	0.110	0.134	0.161
	Severity Profile	0 1 3 3	0 0 4 3	0 1 5 1
	JT/SW P-Value	0.072	0.082	0.113
	RTE P-Value	0.108	0.085	0.108
Pancreas * Pigmentation	Simple Incidence	29/50 (58.0%)	8/26 (30.8%)	15/25 (60.0%)
	Poly-K Incidence	29/45.0 (64.4%)	8/20.4 (39.2%)	15/22.7 (66.0%)
	Terminal Incidence	8/15 (53.3%)	2/9 (22.2%)	7/12 (58.3%)
	Time-to-First	72	399	413
	Poly-K P-Value	0.480N	0.045N*	0.558
	Severity Profile	16 13 0 0	6 2 0 0	11 4 0 0
	JT/SW P-Value	0.181N	0.008N** ¹	0.102N
	RTE P-Value	0.392N	0.008N**	0.392N
Cardiovascular System				
Blood Vessel * Mineralization	Simple Incidence	1/50 (2.0%)	2/26 (7.7%)	0/26 (0.0%)
	Poly-K Incidence	1/34.1 (2.9%)	2/17.8 (11.2%)	0/19.6 (0.0%)
	Terminal Incidence	0/15 (0.0%)	1/9 (11.1%)	0/12 (0.0%)
	Time-to-First	633	671	---
	Poly-K P-Value	0.519N	0.278	0.612N
	Severity Profile	0 0 0 1	0 0 1 1	---
	JT/SW P-Value	0.479N	0.882N	0.371N
	RTE P-Value	0.311N	0.129	0.311N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 12. Nonneoplasms by Body System for Terminal Sacrifice Males EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Heart * Cardiomyopathy	Simple Incidence	44/50 (88.0%)	24/26 (92.3%)	24/26 (92.3%)
	Poly-K Incidence	44/46.0 (95.6%)	24/24.3 (98.8%)	24/25.3 (95.0%)
	Terminal Incidence	15/15 (100.0%)	9/9 (100.0%)	11/12 (91.7%)
	Time-to-First	225	369	413
	Poly-K P-Value	0.644N	0.491	0.708N
	Severity Profile	12 21 10 1	11 8 3 2	5 10 4 5
	JT/SW P-Value	0.150	0.728	0.097
	RTE P-Value	0.079	0.282N	0.079
Heart * Metaplasia,Osseous	Simple Incidence	0/50 (0.0%)	0/26 (0.0%)	2/26 (7.7%)
	Poly-K Incidence	0/33.7 (0.0%)	0/17.6 (0.0%)	2/20.3 (9.8%)
	Terminal Incidence	0/15 (0.0%)	0/9 (0.0%)	1/12 (8.3%)
	Time-to-First	----	----	462
	Poly-K P-Value	0.049 *	-----	0.125
	Severity Profile	---	---	0 0 2 0
	JT/SW P-Value	0.023 *	0.500	0.013 *
	RTE P-Value	0.030 *	0.500	0.030 *
Heart * Mineralization	Simple Incidence	1/50 (2.0%)	2/26 (7.7%)	0/26 (0.0%)
	Poly-K Incidence	1/34.1 (2.9%)	2/17.8 (11.2%)	0/19.6 (0.0%)
	Terminal Incidence	0/15 (0.0%)	1/9 (11.1%)	0/12 (0.0%)
	Time-to-First	633	671	----
	Poly-K P-Value	0.519N	0.278	0.612N
	Severity Profile	0 0 0 1	0 0 1 1	---
	JT/SW P-Value	0.479N	0.882N	0.371N
	RTE P-Value	0.311N	0.134	0.311N
Endocrine System				
Adrenal Cortex * Degeneration,Cystic	Simple Incidence	4/50 (8.0%)	0/26 (0.0%)	1/26 (3.8%)
	Poly-K Incidence	4/33.8 (11.8%)	0/17.6 (0.0%)	1/19.6 (5.1%)
	Terminal Incidence	2/15 (13.3%)	0/9 (0.0%)	1/12 (8.3%)
	Time-to-First	709	----	724 (T)
	Poly-K P-Value	0.217N	0.168N	0.371N
	Severity Profile	0 3 0 1	---	0 0 0 1
	JT/SW P-Value	0.139N	0.071N	0.152N
	RTE P-Value	0.224N	0.086N	0.224N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 12. Nonneoplasms by Body System for Terminal Sacrifice Males EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Adrenal Cortex * Hyperplasia	Simple Incidence	6/50 (12.0%)	0/26 (0.0%)	5/26 (19.2%)
	Poly-K Incidence	6/35.3 (17.0%)	0/17.6 (0.0%)	5/20.2 (24.7%)
	Terminal Incidence	1/15 (6.7%)	0/9 (0.0%)	2/12 (16.7%)
	Time-to-First	559	---	608
	Poly-K P-Value	0.358	0.081N	0.363
	Severity Profile	3 2 1 0	---	3 1 1 0
	JT/SW P-Value	0.350	0.966	0.207
	RTE P-Value	0.171	0.050N*	0.171
Adrenal Cortex * Hypertrophy	Simple Incidence	2/50 (4.0%)	7/26 (26.9%)	2/26 (7.7%)
	Poly-K Incidence	2/34.2 (5.8%)	7/20.0 (35.0%)	2/19.7 (10.2%)
	Terminal Incidence	1/15 (6.7%)	1/9 (11.1%)	1/12 (8.3%)
	Time-to-First	566	369	706
	Poly-K P-Value	0.269	0.005 **	0.482
	Severity Profile	1 1 0 0	1 5 1 0	0 2 0 0
	JT/SW P-Value	0.095	0.001 **	0.041 *
	RTE P-Value	0.295	0.002 **	0.295
Adrenal Cortex * Vacuolization Cytoplasmic	Simple Incidence	18/50 (36.0%)	10/26 (38.5%)	11/26 (42.3%)
	Poly-K Incidence	18/39.6 (45.5%)	10/19.0 (52.6%)	11/21.3 (51.7%)
	Terminal Incidence	5/15 (33.3%)	5/9 (55.6%)	7/12 (58.3%)
	Time-to-First	486	585	462
	Poly-K P-Value	0.351	0.407	0.423
	Severity Profile	7 8 3 0	3 5 1 1	2 8 1 0
	JT/SW P-Value	0.250	0.370	0.300
	RTE P-Value	0.254	0.371	0.254
Adrenal Medulla * Hyperplasia	Simple Incidence	5/50 (10.0%)	5/26 (19.2%)	6/26 (23.1%)
	Poly-K Incidence	5/35.1 (14.2%)	5/17.9 (27.9%)	6/20.2 (29.7%)
	Terminal Incidence	1/15 (6.7%)	3/9 (33.3%)	4/12 (33.3%)
	Time-to-First	578	671	559
	Poly-K P-Value	0.102	0.200	0.143
	Severity Profile	3 2 0 0	2 0 3 0	4 2 0 0
	JT/SW P-Value	0.061	0.111	0.091
	RTE P-Value	0.081	0.124	0.081

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 12. Nonneoplasms by Body System for Terminal Sacrifice Males EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Parathyroid Gland * Hyperplasia	Simple Incidence	11/49 (22.4%)	7/25 (28.0%)	11/25 (44.0%)
	Poly-K Incidence	11/36.7 (30.0%)	7/18.2 (38.4%)	11/20.9 (52.7%)
	Terminal Incidence	3/15 (20.0%)	3/9 (33.3%)	5/12 (41.7%)
	Time-to-First	543	630	559
	Poly-K P-Value	0.051	0.372	0.066
	Severity Profile	3 7 0 1	2 3 1 1	3 5 1 2
	JT/SW P-Value	0.030 *	0.279	0.027 *
	RTE P-Value	0.029 *	0.287	0.029 *
Pituitary Gland * Angiectasis	Simple Incidence	6/48 (12.5%)	7/26 (26.9%)	3/26 (11.5%)
	Poly-K Incidence	6/33.5 (17.9%)	7/19.1 (36.6%)	3/20.1 (14.9%)
	Terminal Incidence	1/14 (7.1%)	3/9 (33.3%)	2/12 (16.7%)
	Time-to-First	494	543	559
	Poly-K P-Value	0.544N	0.111	0.537N
	Severity Profile	0 0 0 6	0 0 3 4	0 0 0 3
	JT/SW P-Value	0.390	0.083	0.301
	RTE P-Value	0.456N	0.080	0.456N
Pituitary Gland * Cyst,Pars Distalis	Simple Incidence	8/48 (16.7%)	2/26 (7.7%)	4/26 (15.4%)
	Poly-K Incidence	8/34.9 (22.9%)	2/18.8 (10.7%)	4/20.9 (19.2%)
	Terminal Incidence	1/14 (7.1%)	0/9 (0.0%)	2/12 (16.7%)
	Time-to-First	284	543	473
	Poly-K P-Value	0.393N	0.229N	0.502N
Pituitary Gland * Hyperplasia,Pars Distalis	Simple Incidence	11/48 (22.9%)	10/26 (38.5%)	13/26 (50.0%)
	Poly-K Incidence	11/36.2 (30.4%)	10/21.2 (47.1%)	13/22.6 (57.6%)
	Terminal Incidence	4/14 (28.6%)	3/9 (33.3%)	8/12 (66.7%)
	Time-to-First	467	399	413
	Poly-K P-Value	0.020 *	0.152	0.027 *
	Severity Profile	3 4 4 0	2 4 4 0	3 7 3 0
	JT/SW P-Value	0.012 *	0.075	0.017 *
	RTE P-Value	0.016 *	0.077	0.016 *
Pituitary Gland * Hypertrophy,Pars Distalis	Simple Incidence	4/48 (8.3%)	2/26 (7.7%)	2/26 (7.7%)
	Poly-K Incidence	4/33.1 (12.1%)	2/18.1 (11.0%)	2/20.3 (9.8%)
	Terminal Incidence	2/14 (14.3%)	1/9 (11.1%)	0/12 (0.0%)
	Time-to-First	585	581	608
	Poly-K P-Value	0.494N	0.635N	0.578N
	Severity Profile	1 3 0 0	1 1 0 0	0 2 0 0
	JT/SW P-Value	0.462N	0.452N	0.542N
	RTE P-Value	0.471N	0.453N	0.471N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 12. Nonneoplasms by Body System for Terminal Sacrifice Males EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Thyroid Gland * Hyperplasia,C-Cell	Simple Incidence	9/46 (19.6%)	12/25 (48.0%)	7/25 (28.0%)
	Poly-K Incidence	9/34.9 (25.8%)	12/20.3 (59.1%)	7/20.2 (34.6%)
	Terminal Incidence	5/15 (33.3%)	4/9 (44.4%)	5/12 (41.7%)
	Time-to-First	225	459	590
	Poly-K P-Value	0.196	0.009 **	0.345
	Severity Profile	5 2 2 0	4 8 0 0	5 1 1 0
	JT/SW P-Value	0.121	0.006 ** 1	0.065
	RTE P-Value	0.268	0.007 **	0.268
Thyroid Gland * Hyperplasia,Follicular Cell	Simple Incidence	3/46 (6.5%)	2/25 (8.0%)	3/25 (12.0%)
	Poly-K Incidence	3/32.5 (9.2%)	2/17.7 (11.3%)	3/19.9 (15.1%)
	Terminal Incidence	2/15 (13.3%)	1/9 (11.1%)	1/12 (8.3%)
	Time-to-First	720	577	639
	Poly-K P-Value	0.341	0.601	0.420
	Severity Profile	0 2 1 0	0 1 0 1	0 1 2 0
	JT/SW P-Value	0.218	0.398	0.246
	RTE P-Value	0.208	0.403	0.208
Thyroid Gland * Ultimobranchial Cyst	Simple Incidence	7/46 (15.2%)	1/25 (4.0%)	3/25 (12.0%)
	Poly-K Incidence	7/34.4 (20.3%)	1/17.2 (5.8%)	3/19.7 (15.2%)
	Terminal Incidence	2/15 (13.3%)	1/9 (11.1%)	2/12 (16.7%)
	Time-to-First	225	725 (T)	608
	Poly-K P-Value	0.326N	0.172N	0.458N
Genital System				
Epididymis * Exfoliated Germ Cell	Simple Incidence	10/49 (20.4%)	6/26 (23.1%)	4/26 (15.4%)
	Poly-K Incidence	10/36.5 (27.4%)	6/18.3 (32.8%)	4/20.4 (19.7%)
	Terminal Incidence	3/15 (20.0%)	3/9 (33.3%)	1/12 (8.3%)
	Time-to-First	494	630	590
	Poly-K P-Value	0.347N	0.459	0.369N
	Severity Profile	5 3 1 1	4 1 1 0	3 1 0 0
	JT/SW P-Value	0.312N	0.574N	0.321N
	RTE P-Value	0.271N	0.421	0.271N
Epididymis * Hypospermia	Simple Incidence	11/49 (22.4%)	5/26 (19.2%)	10/26 (38.5%)
	Poly-K Incidence	11/37.0 (29.7%)	5/19.4 (25.8%)	10/20.6 (48.4%)
	Terminal Incidence	2/15 (13.3%)	2/9 (22.2%)	6/12 (50.0%)
	Time-to-First	225	369	559
	Poly-K P-Value	0.111	0.501N	0.119
	Severity Profile	0 0 0 11	0 0 1 4	0 0 0 10
	JT/SW P-Value	0.110	0.658	0.076
RTE P-Value	0.072	0.345N	0.072	

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 12. Nonneoplasms by Body System for Terminal Sacrifice Males EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Epididymis * Infiltration Cellular,Lymphocyte	Simple Incidence	10/49 (20.4%)	5/26 (19.2%)	10/26 (38.5%)
	Poly-K Incidence	10/35.5 (28.1%)	5/18.3 (27.3%)	10/20.4 (49.1%)
	Terminal Incidence	4/15 (26.7%)	2/9 (22.2%)	7/12 (58.3%)
	Time-to-First	225	607	590
	Poly-K P-Value	0.076	0.602N	0.087
	Severity Profile	8 2 0 0	4 1 0 0	8 2 0 0
	JT/SW P-Value	0.072	0.548	0.051
	RTE P-Value	0.045 *	0.456N	0.045 *
Prostate, Dorsal/Lateral Lobe * Fibrosis	Simple Incidence	9/50 (18.0%)	2/26 (7.7%)	2/25 (8.0%)
	Poly-K Incidence	9/36.6 (24.6%)	2/17.6 (11.4%)	2/19.4 (10.3%)
	Terminal Incidence	3/15 (20.0%)	2/9 (22.2%)	1/12 (8.3%)
	Time-to-First	526	725 (T)	710
	Poly-K P-Value	0.102N	0.220N	0.172N
	Severity Profile	0 7 0 2	0 1 0 1	0 0 1 1
	JT/SW P-Value	0.094N	0.124N	0.149N
	RTE P-Value	0.136N	0.117N	0.136N
Prostate, Dorsal/Lateral Lobe * Infiltration Cellular,Lymphocyte	Simple Incidence	33/50 (66.0%)	17/26 (65.4%)	13/25 (52.0%)
	Poly-K Incidence	33/40.4 (81.7%)	17/21.3 (79.7%)	13/20.1 (64.6%)
	Terminal Incidence	13/15 (86.7%)	9/9 (100.0%)	10/12 (83.3%)
	Time-to-First	520	369	518
	Poly-K P-Value	0.074N	0.568N	0.091N
	Severity Profile	19 11 2 1	10 6 1 0	6 6 0 1
	JT/SW P-Value	0.237N	0.447N	0.259N
	RTE P-Value	0.219N	0.449N	0.219N
Prostate, Dorsal/Lateral Lobe * Inflammation,Suppurative	Simple Incidence	41/50 (82.0%)	26/26 (100.0%)	22/25 (88.0%)
	Poly-K Incidence	41/45.6 (89.9%)	26/26.0 (100.0%)	22/23.1 (95.4%)
	Terminal Incidence	14/15 (93.3%)	9/9 (100.0%)	12/12 (100.0%)
	Time-to-First	284	369	413
	Poly-K P-Value	0.138	0.083	0.352
	Severity Profile	8 26 4 3	8 16 1 1	6 12 3 1
	JT/SW P-Value	0.424	0.370	0.485
	RTE P-Value	0.455	0.369	0.455

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 12. Nonneoplasms by Body System for Terminal Sacrifice Males EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Prostate, Ventral Lobe * Atrophy	Simple Incidence	4/50 (8.0%)	2/26 (7.7%)	0/26 (0.0%)
	Poly-K Incidence	4/34.9 (11.5%)	2/18.6 (10.7%)	0/19.6 (0.0%)
	Terminal Incidence	2/15 (13.3%)	0/9 (0.0%)	0/12 (0.0%)
	Time-to-First	526	561	----
	Poly-K P-Value	0.123N	0.646N	0.150N
	Severity Profile	0 0 3 1	0 2 0 0	---
	JT/SW P-Value	0.098N	0.444N	0.091N
	RTE P-Value	0.055N	0.447N	0.055N
Prostate, Ventral Lobe * Fibrosis	Simple Incidence	15/50 (30.0%)	2/26 (7.7%)	6/26 (23.1%)
	Poly-K Incidence	15/36.0 (41.7%)	2/18.1 (11.0%)	6/20.5 (29.3%)
	Terminal Incidence	7/15 (46.7%)	1/9 (11.1%)	3/12 (25.0%)
	Time-to-First	549	581	590
	Poly-K P-Value	0.135N	0.018N*	0.252N
	Severity Profile	0 7 3 5	0 1 0 1	0 5 0 1
	JT/SW P-Value	0.092N	0.015N* ¹	0.074N
	RTE P-Value	0.191N	0.011N*	0.191N
Prostate, Ventral Lobe * Hyperplasia,Epithelium	Simple Incidence	10/50 (20.0%)	4/26 (15.4%)	7/26 (26.9%)
	Poly-K Incidence	10/34.0 (29.4%)	4/17.6 (22.7%)	7/19.9 (35.2%)
	Terminal Incidence	6/15 (40.0%)	4/9 (44.4%)	6/12 (50.0%)
	Time-to-First	674	725 (T)	639
	Poly-K P-Value	0.412	0.427N	0.443
	Severity Profile	1 6 3 0	0 1 2 1	1 4 2 0
	JT/SW P-Value	0.310	0.621	0.303
	RTE P-Value	0.255	0.389N	0.255
Prostate, Ventral Lobe * Infiltration Cellular,Lymphocyte	Simple Incidence	25/50 (50.0%)	6/26 (23.1%)	14/26 (53.8%)
	Poly-K Incidence	25/40.8 (61.2%)	6/19.2 (31.3%)	14/22.3 (62.9%)
	Terminal Incidence	10/15 (66.7%)	2/9 (22.2%)	8/12 (66.7%)
	Time-to-First	72	543	462
	Poly-K P-Value	0.488N	0.022N*	0.561
	Severity Profile	12 5 5 3	5 0 1 0	6 7 0 1
	JT/SW P-Value	0.309N	0.006N** ¹	0.148N
	RTE P-Value	0.426	0.005N**	0.426

RR9: CLARITY-BPA Core Study

Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 12. Nonneoplasms by Body System for Terminal Sacrifice Males EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Prostate, Ventral Lobe * Inflammation,Suppurative	Simple Incidence	16/50 (32.0%)	4/26 (15.4%)	8/26 (30.8%)
	Poly-K Incidence	16/38.1 (42.0%)	4/18.7 (21.4%)	8/22.2 (36.0%)
	Terminal Incidence	5/15 (33.3%)	2/9 (22.2%)	2/12 (16.7%)
	Time-to-First	543	369	413
	Poly-K P-Value	0.316N	0.103N	0.424N
	Severity Profile	7 2 2 5	3 0 0 1	5 2 0 1
	JT/SW P-Value	0.240N	0.050N	0.194N
	RTE P-Value	0.378N	0.045N*	0.378N
Prostate, Ventral Lobe * Mineralization	Simple Incidence	4/50 (8.0%)	1/26 (3.8%)	3/26 (11.5%)
	Poly-K Incidence	4/34.0 (11.8%)	1/17.9 (5.6%)	3/20.3 (14.8%)
	Terminal Incidence	2/15 (13.3%)	0/9 (0.0%)	1/12 (8.3%)
	Time-to-First	671	638	590
	Poly-K P-Value	0.489	0.411N	0.538
	Severity Profile	0 0 3 1	0 0 1 0	0 1 1 1
	JT/SW P-Value	0.391	0.758	0.359
	RTE P-Value	0.303	0.260N	0.303
Seminal Vesicle * Dilatation,Lumen	Simple Incidence	2/44 (4.5%)	2/25 (8.0%)	1/23 (4.3%)
	Poly-K Incidence	2/31.7 (6.3%)	2/17.4 (11.5%)	1/17.9 (5.6%)
	Terminal Incidence	1/15 (6.7%)	1/9 (11.1%)	1/12 (8.3%)
	Time-to-First	720	665	727 (T)
	Poly-K P-Value	0.616N	0.464	0.698N
	Severity Profile	0 0 0 2	0 1 1 0	0 0 0 1
	JT/SW P-Value	0.452	0.300	0.471
	RTE P-Value	0.486N	0.296	0.486N
Seminal Vesicle * Hyperplasia,Epithelium	Simple Incidence	7/44 (15.9%)	0/25 (0.0%)	2/23 (8.7%)
	Poly-K Incidence	7/32.7 (21.4%)	0/17.2 (0.0%)	2/18.4 (10.8%)
	Terminal Incidence	5/15 (33.3%)	0/9 (0.0%)	1/12 (8.3%)
	Time-to-First	558	---	559
	Poly-K P-Value	0.136N	0.048N*	0.280N
	Severity Profile	0 5 1 1	---	0 1 1 0
	JT/SW P-Value	0.082N	0.018N* ¹	0.076N
	RTE P-Value	0.177N	0.012N*	0.177N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 12. Nonneoplasms by Body System for Terminal Sacrifice Males EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Testes * Degeneration,Seminiferous Tubule	Simple Incidence	40/49 (81.6%)	17/26 (65.4%)	21/26 (80.8%)
	Poly-K Incidence	40/44.6 (89.8%)	17/21.5 (79.1%)	21/22.9 (91.8%)
	Terminal Incidence	14/15 (93.3%)	8/9 (88.9%)	12/12 (100.0%)
	Time-to-First	225	369	518
	Poly-K P-Value	0.592	0.166N	0.584
	Severity Profile	20 5 5 10	8 4 1 4	8 2 1 10
	JT/SW P-Value	0.348	0.890	0.240
	RTE P-Value	0.192	0.126N	0.192
Testes * Polyarteritis	Simple Incidence	12/49 (24.5%)	6/26 (23.1%)	5/26 (19.2%)
	Poly-K Incidence	12/35.2 (34.1%)	6/18.7 (32.1%)	5/20.1 (24.9%)
	Terminal Incidence	6/15 (40.0%)	2/9 (22.2%)	4/12 (33.3%)
	Time-to-First	494	607	590
	Poly-K P-Value	0.292N	0.564N	0.338N
	Severity Profile	1 5 1 5	1 3 1 1	2 1 1 1
	JT/SW P-Value	0.256N	0.394N	0.303N
	RTE P-Value	0.256N	0.397N	0.256N
Hematopoietic System				
Bone Marrow * Hyperplasia,Myeloid Cell	Simple Incidence	6/48 (12.5%)	3/26 (11.5%)	2/25 (8.0%)
	Poly-K Incidence	6/35.1 (17.1%)	3/19.2 (15.6%)	2/20.4 (9.8%)
	Terminal Incidence	1/15 (6.7%)	1/9 (11.1%)	0/12 (0.0%)
	Time-to-First	520	369	413
	Poly-K P-Value	0.303N	0.596N	0.363N
	Severity Profile	0 1 1 4	0 0 1 2	0 0 1 1
	JT/SW P-Value	0.294N	0.456N	0.333N
	RTE P-Value	0.281N	0.455N	0.281N
Bone Marrow * Hypocellularity	Simple Incidence	5/48 (10.4%)	0/26 (0.0%)	1/25 (4.0%)
	Poly-K Incidence	5/33.3 (15.0%)	0/17.6 (0.0%)	1/19.3 (5.2%)
	Terminal Incidence	3/15 (20.0%)	0/9 (0.0%)	1/12 (8.3%)
	Time-to-First	616	---	727 (T)
	Poly-K P-Value	0.127N	0.109N	0.260N
	Severity Profile	0 0 5 0	---	0 0 1 0
	JT/SW P-Value	0.075N	0.045N* ¹	0.090N
	RTE P-Value	0.125N	0.032N*	0.125N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 12. Nonneoplasms by Body System for Terminal Sacrifice Males EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Spleen * Hematopoietic Cell Proliferation	Simple Incidence	13/49 (26.5%)	6/26 (23.1%)	7/25 (28.0%)
	Poly-K Incidence	13/37.2 (35.0%)	6/18.9 (31.8%)	7/20.7 (33.8%)
	Terminal Incidence	4/15 (26.7%)	2/9 (22.2%)	4/12 (33.3%)
	Time-to-First	225	551	462
	Poly-K P-Value	0.516N	0.524N	0.582N
	Severity Profile	5 3 3 2	2 2 2 0	3 3 1 0
	JT/SW P-Value	0.460N	0.363N	0.507N
	RTE P-Value	0.499N	0.366N	0.499N
Spleen * Pigmentation	Simple Incidence	28/49 (57.1%)	16/26 (61.5%)	16/25 (64.0%)
	Poly-K Incidence	28/40.3 (69.4%)	16/20.8 (76.9%)	16/22.5 (71.2%)
	Terminal Incidence	12/15 (80.0%)	8/9 (88.9%)	9/12 (75.0%)
	Time-to-First	284	369	462
	Poly-K P-Value	0.472	0.363	0.562
	Severity Profile	5 15 4 4	8 6 1 1	5 10 0 1
	JT/SW P-Value	0.377N	0.267N	0.400N
	RTE P-Value	0.432N	0.254N	0.432N
Thymus * Atrophy	Simple Incidence	47/50 (94.0%)	22/24 (91.7%)	24/25 (96.0%)
	Poly-K Incidence	47/48.2 (97.5%)	22/22.3 (98.7%)	24/24.3 (98.9%)
	Terminal Incidence	15/15 (100.0%)	9/9 (100.0%)	11/11 (100.0%)
	Time-to-First	225	369	413
	Poly-K P-Value	0.503	0.748	0.715
	Severity Profile	0 2 1 44	0 0 2 20	0 1 1 22
	JT/SW P-Value	0.455N	0.307N	0.481N
	RTE P-Value	0.485	0.306N	0.485
Integumentary System				
Mammary Gland * Degeneration,Alveolus	Simple Incidence	28/50 (56.0%)	14/25 (56.0%)	17/25 (68.0%)
	Poly-K Incidence	28/40.6 (69.0%)	14/19.0 (73.6%)	17/22.2 (76.4%)
	Terminal Incidence	11/15 (73.3%)	8/8 (100.0%)	8/12 (66.7%)
	Time-to-First	284	543	462
	Poly-K P-Value	0.291	0.474	0.357
	Severity Profile	0 1 10 17	0 2 3 9	0 2 4 11
	JT/SW P-Value	0.214	0.507	0.214
	RTE P-Value	0.183	0.493N	0.183

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 12. Nonneoplasms by Body System for Terminal Sacrifice Males EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Mammary Gland * Dilatation,Alveolus	Simple Incidence	8/50 (16.0%)	4/25 (16.0%)	1/25 (4.0%)
	Poly-K Incidence	8/35.0 (22.9%)	4/17.6 (22.7%)	1/19.3 (5.2%)
	Terminal Incidence	3/15 (20.0%)	1/8 (12.5%)	1/12 (8.3%)
	Time-to-First	558	607	727 (T)
	Poly-K P-Value	0.082N	0.632N	0.089N
	Severity Profile	0 5 3 0	1 1 2 0	0 1 0 0
	JT/SW P-Value	0.100N	0.496N	0.082N
	RTE P-Value	0.063N	0.496N	0.063N
Mammary Gland * Dilatation,Duct	Simple Incidence	14/50 (28.0%)	6/25 (24.0%)	2/25 (8.0%)
	Poly-K Incidence	14/35.7 (39.2%)	6/17.9 (33.6%)	2/20.0 (10.0%)
	Terminal Incidence	6/15 (40.0%)	2/8 (25.0%)	1/12 (8.3%)
	Time-to-First	549	607	518
	Poly-K P-Value	0.014N*	0.459N	0.016N*
	Severity Profile	0 8 6 0	0 4 2 0	0 2 0 0
	JT/SW P-Value	0.028N*	0.337N	0.023N*
	RTE P-Value	0.018N*	0.327N	0.018N*
Mammary Gland * Hyperplasia,Lobular	Simple Incidence	1/50 (2.0%)	2/25 (8.0%)	0/25 (0.0%)
	Poly-K Incidence	1/34.4 (2.9%)	2/18.3 (10.9%)	0/19.3 (0.0%)
	Terminal Incidence	0/15 (0.0%)	0/8 (0.0%)	0/12 (0.0%)
	Time-to-First	486	369	----
	Poly-K P-Value	0.525N	0.281	0.617N
	Severity Profile	0 1 0 0	0 2 0 0	---
	JT/SW P-Value	0.500	0.107	0.378
	RTE P-Value	0.317N	0.108	0.317N
Nervous System				
Brain, Brain Stem * Compression	Simple Incidence	12/49 (24.5%)	6/26 (23.1%)	4/26 (15.4%)
	Poly-K Incidence	12/35.7 (33.6%)	6/19.0 (31.5%)	4/20.8 (19.3%)
	Terminal Incidence	4/15 (26.7%)	2/9 (22.2%)	2/12 (16.7%)
	Time-to-First	558	543	518
	Poly-K P-Value	0.163N	0.560N	0.190N
	Severity Profile	3 2 4 3	0 2 4 0	0 1 2 1
	JT/SW P-Value	0.225N	0.447N	0.246N
	RTE P-Value	0.208N	0.443N	0.208N

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

Table 12. Nonneoplasms by Body System for Terminal Sacrifice Males EE2 Continuous Dose Arm				
System and Nonneoplasm	Treatment (ug/kg)			
Lesion	Statistic	Control	0.05	0.50
Brain, Cerebrum * Dilatation,Ventricle	Simple Incidence	6/50 (12.0%)	2/26 (7.7%)	4/26 (15.4%)
	Poly-K Incidence	6/35.8 (16.7%)	2/18.2 (11.0%)	4/20.2 (19.8%)
	Terminal Incidence	0/15 (0.0%)	0/9 (0.0%)	3/12 (25.0%)
	Time-to-First	558	630	518
	Poly-K P-Value	0.493	0.437N	0.532
	Severity Profile	2 4 0 0	0 2 0 0	1 3 0 0
	JT/SW P-Value	0.402	0.704	0.390
	RTE P-Value	0.329	0.308N	0.329
Urinary System				
Kidney * Cyst,Cortex	Simple Incidence	20/50 (40.0%)	11/26 (42.3%)	8/26 (30.8%)
	Poly-K Incidence	20/37.8 (53.0%)	11/20.4 (53.9%)	8/20.7 (38.7%)
	Terminal Incidence	9/15 (60.0%)	5/9 (55.6%)	5/12 (41.7%)
	Time-to-First	494	369	559
	Poly-K P-Value	0.192N	0.588	0.208N
Kidney * Cyst,Renal Tubule	Simple Incidence	11/50 (22.0%)	14/26 (53.8%)	10/26 (38.5%)
	Poly-K Incidence	11/37.4 (29.4%)	14/20.6 (67.9%)	10/21.1 (47.3%)
	Terminal Incidence	3/15 (20.0%)	7/9 (77.8%)	6/12 (50.0%)
	Time-to-First	284	369	462
	Poly-K P-Value	0.054	0.002 **	0.128
Kidney * Hyperplasia,Transitional Epithelium	Simple Incidence	3/50 (6.0%)	2/26 (7.7%)	1/26 (3.8%)
	Poly-K Incidence	3/34.6 (8.7%)	2/17.8 (11.2%)	1/19.7 (5.1%)
	Terminal Incidence	1/15 (6.7%)	1/9 (11.1%)	0/12 (0.0%)
	Time-to-First	543	671	710
	Poly-K P-Value	0.448N	0.578	0.523N
	Severity Profile	1 1 1 0	1 1 0 0	0 0 1 0
	JT/SW P-Value	0.409N	0.601N	0.431N
	RTE P-Value	0.365N	0.395	0.365N
Kidney * Infiltration Cellular,Polymorphonuclear	Simple Incidence	6/50 (12.0%)	2/26 (7.7%)	5/26 (19.2%)
	Poly-K Incidence	6/35.3 (17.0%)	2/17.8 (11.2%)	5/19.6 (25.5%)
	Terminal Incidence	3/15 (20.0%)	1/9 (11.1%)	5/12 (41.7%)
	Time-to-First	543	679	724 (T)
	Poly-K P-Value	0.309	0.441N	0.341
	Severity Profile	4 1 1 0	2 0 0 0	3 2 0 0
	JT/SW P-Value	0.264	0.731	0.220
	RTE P-Value	0.191	0.283N	0.191

RR9: CLARITY-BPA Core Study
Data from 34-Appendix XXXIV Terminal Sacrifice Lesion Incidence Statistical Report – Non-Neoplastic

<i>Table 12. Nonneoplasms by Body System for Terminal Sacrifice Males EE2 Continuous Dose Arm</i>				
<i>System and Nonneoplasm</i>	<i>Treatment (ug/kg)</i>			
<i>Lesion</i>	<i>Statistic</i>	<i>Control</i>	<i>0.05</i>	<i>0.50</i>
Kidney * Nephropathy	Simple Incidence	44/50 (88.0%)	21/26 (80.8%)	23/26 (88.5%)
	Poly-K Incidence	44/46.4 (94.8%)	21/22.5 (93.2%)	23/24.5 (93.7%)
	Terminal Incidence	15/15 (100.0%)	9/9 (100.0%)	11/12 (91.7%)
	Time-to-First	225	459	413
	Poly-K P-Value	0.527N	0.635N	0.662N
	Severity Profile	11 12 6 15	1 6 9 5	3 8 7 5
	JT/SW P-Value	0.449	0.433	0.512
	RTE P-Value	0.457	0.416	0.457

P-values for dose trend are presented in the “Control” column.

N indicates a negative trend or negative treatment comparison to control with corresponding lower-tail p-values.

¹ Nonsignificant SW test due to the assumption of monotonicity.