PROFILE and FDA Data Comparison

All PROFILE Data (as of 1/20/2020) (n=131)				All MDR Reports (as of 9/30/2018 (n=457)		All MDR Reports (as of 7/6/2019 (n=573)	
Age at time of diagnosis (yrs)	Median	54		Median	53	Median	53
	Range	28-84		Range	24-90	Range	24-90
	Not specified	3		Not specified (# of reports)	111 (24%)	Not specified (# of reports)	161 (28%)
Time from the last Implant ("Current implant" for PROFILE) to ALCL Diagnosis (yrs)	Median	9		Median	9	Median	8
	Range	.08-27		Range	0-34	Range	0-34
	Not specified	25		Not specified (# of reports)	110 (24%)	Not specified (# of reports)	169 (29%)
		N	**%**	**N**	**%**	**N**	**%**
Implant Surface*	Textured	99	**76**	310	**68**	385	**67**
	Smooth	10	**8**	24	**5**	26	**5**
	Polyurethane	1	**1**	n/a	**n/a**	n/a	**n/a**
	Not specified	21	**16**	123	**27**	162	**28**
Implant Fill	Silicone	72	**55**	274	**60**	343	**60**
	Saline	50	**38**	183	**40**	197	**34**
	Saline/Silicone	2	**2**	n/a	**n/a**	n/a	**n/a**
	Polyureathane foam	1	**1**	n/a	**n/a**	n/a	**n/a**
	Not specified	6	**5**	0	**0**	33	**6**
Reason for Implant	Reconstruction	55	**42**	108	**24**	115	**20**
	Augmentation	69	**53**	104	**23**	111	**19**
	Not specified	6	**5**	245	**54**	347	**61**
	Unknown	1	**1**	n/a	**n/a**	n/a	**n/a**
Clinical Presentation (breast)**	Seroma	104	**79**	266	**58**	302	**53**
	Breast swelling/pain	n/a	**n/a**	135	**30**	150	**26**
	Capsular contracture	41	**31**	69	**15**	73	**13**
	Peri-implant mass/lump (Palpable Mass: PROFILE)	18	**14**	82	**18**	94	**16**
	Other	n/a	**n/a**	43	**9**	56	**10**
	Not specified/uncertain	n/a	**n/a**	105	**23**	147	**26**
Anaplastic lymphoma kinase (ALK)	Positive	0	**0**	0	**0**	0	**0**
	Negative	97	**74**	229	**50**	255	**45**
	Not specified	21	**16**	228	**50**	318	**55**
	Unknown	13	**10**	n/a	**n/a**	n/a	**n/a**
CD30 Status***	Positive	107	**82**	215	**47**	246	**43**
	Negative	0	**0**	0	**0**	0	**0**
	Not Specified	1	**1**	242	**53**	327	**57**
	Unknown	23	**18**	n/a	**n/a**	n/a	**n/a**
Implant Manufacturer	Allergan includes McGhan, Inamed	82	**63**	386	**84**	481	**84**
	Mentor	17	**13**	36	**8**	38	**7**
	Sientra	3	**2**	2	**0.4**	6	**1**
	Other****	2	**2**	5	**1**	6	**1**
	Unknown	1	**1**	28	**6**	42	**7**
	Not Reported	26	**20**	0	**0**	0	**0**
Reporter Country: US or OUS***	US	131	**100**	276	**48**	320	**56**
	OUS	n/a	**n/a**	181	**32**	253	**44**
	Not Specified	0	**0**	0	**0**	0	**0**

*9 of the 10 "smooth" cases reported to PROFILE had a reported clinical history of a textured device. PROFILE Team in the process of following up with reporting physician to obtain additional information for the remaining "smooth" case. In the 26 cases of smooth implants reported to FDA, 12 have unknown prior history of implants, 7 have a history of textured implants, and 7 have a history of prior implants with an unknown texture. There are no reports of cases associated with tissue expanders.

**MDRs and PROFILE data sometime list more than one clinical presentation, e.g. seroma and peri-implant mass/lump, in which two presentations were counted.

***CD30 is a cell membrane protein associated with diagnosis of classic Hodgkin's Lymphoma and BIA-ALCL.

****Other Manufacturers include: Bristol Myers Squib, Nagor, Polytech Silimed, Silimed and Sientra/Silimed

*****US/OUS is counted as the recorded reporter's country in the MedWatch form, or if the event was noted to be from a foreign source in box G3 of the MedWatch form. Please note that the reporter country may not reflect the country where the event occurred or the country where the device is marketed.