

16.2.4 Demographic Data

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,			Exemption Granted?	If Yes, Date Granted
			Category	Inclusion/Exclusion Number	Explanation		
R1001	2009-02-18	Yes					
R1002	2009-02-18	Yes					
R1003	2009-02-18	Yes					
R1004	2009-03-02	Yes					
R1005	2009-03-02	Yes					
R1006	2009-03-03	Yes					
R1007	2009-03-05	Yes					
R1008	2009-03-02	Yes					
R1009	2009-03-02	Yes					
R1010	2009-03-19	Yes					

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Explanation		
R1011	2009-04-03	Yes				
R1012	2009-04-01	Yes				
R1013	2009-04-08	Yes				
R1014	2009-04-08	Yes				
R1015	2009-04-16	Yes				
R1016	2009-05-08	Yes				
R1017	2009-05-08	Yes				
R1018	2009-05-06	Yes				
R1019	2009-05-08	Yes				
R1020	2009-05-29	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Explanation		
R1021	2009-05-29	Yes				
R1022	2009-05-29	Yes				
R1023	2009-06-11	Yes				
R1024	2009-06-16	Yes				
R1025	2009-06-16	Yes				
R1026	2009-06-16	Yes				
R1027	2009-06-25	Yes				
R1028	2009-06-25	Yes				
R1029	2009-06-25	Yes				
R1030	2009-07-07	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Inclusion/Exclusion Number		
R1031	2009-07-09	Yes				
R1032	2009-07-09	Yes				
R1033	2009-07-07	Yes				
R1034	2009-07-23	Yes				
R1035	2009-07-28	Yes				
R1036	2009-07-28	No	Inclusion	6	Subject Does Not Have Regular Dental Check Ups (Subject Has Upper And Lower Dentures)	Yes 2009-07-30
R1037	2009-07-28	Yes				
R2001	2009-03-05	Yes				
R2002	2009-03-06	Yes				
R2003	2009-03-05	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Explanation		
R2004	2009-03-11	Yes				
R2005	2009-03-12	Yes				
R2006	2009-03-12	Yes				
R2007	2009-04-07	Yes				
R2008	2009-04-07	Yes				
R2009	2009-04-08	Yes				
R2010	2009-04-09	Yes				
R2011	2009-04-10	Yes				
R2012	2009-04-15	Yes				
R2013	2009-04-15	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Explanation		
R2014	2009-04-24	Yes				
R2015	2009-04-23	Yes				
R2016	2009-04-24	Yes				
R2017	2009-04-27	Yes				
R2018	2009-05-07	Yes				
R2019	2009-05-12	Yes				
R2020	2009-05-14	Yes				
R2021	2009-05-27	Yes				
R2022	2009-06-18	Yes				
R2023	2009-06-18	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Explanation		
R2024	2009-06-26	Yes				
R2025	2009-06-29	Yes				
R2026	2009-06-30	Yes				
R2027	2009-07-01	Yes				
R2028	2009-07-08	Yes				
R2029	2009-07-09	Yes				
R2030	2009-07-16	Yes				
R2031	2009-07-20	Yes				
R2032	2009-07-20	Yes				
R3001	2009-02-18	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Explanation		
R3002	2009-02-23	Yes				
R3003	2009-02-23	Yes				
R3004	2009-02-18	Yes				
R3005	2009-02-25	Yes				
R3006	2009-02-25	Yes				
R3007	2009-02-25	Yes				
R3008	2009-02-18	Yes				
R3009	2009-02-25	Yes				
R3010	2009-03-05	Yes				
R3011	2009-03-12	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Number Explanation		
R3012	2009-03-26	Yes				
R3013	2009-03-26	Yes				
R3014	2009-03-26	Yes				
R3015	2009-03-26	Yes				
R3016	2009-03-31	Yes				
R3017	2009-04-08	Yes				
R3018	2009-04-08	Yes				
R3019	2009-04-16	Yes				
R3020	2009-04-23	Yes				
R3021	2009-04-23	No	Inclusion	6 Subject Does Not Have Regular Dental Check Ups Due To Full Upper And Lower Dentures.	Yes	2009-04-29

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Number Explanation		
R3022	2009-04-30	Yes				
R3023	2009-04-30	Yes				
R3024	2009-04-29	No	Inclusion	6 Subject Has Full Dentures And Does Not Get Regular Dental Check Ups	Yes	2009-05-05
R3025	2009-05-06	Yes				
R3026	2009-05-07	Yes				
R3027	2009-05-06	Yes				
R3028	2009-05-07	Yes				
R3029	2009-05-06	Yes				
R3030	2009-05-07	Yes				
R3031	2009-05-06	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Explanation		
R3032	2009-05-07	Yes				
R4001	2009-02-20	Yes				
R4002	2009-02-20	Yes				
R4003	2009-02-20	Yes				
R4004	2009-02-25	Yes				
R4005	2009-02-25	Yes				
R4006	2009-03-08	Yes				
R4007	2009-03-03	Yes				
R4008	2009-02-26	Yes				
R4009	2009-02-26	Yes				

NOTE: For the criteria definition, see the Protocol.

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Number Explanation		
R4010	2009-02-26	Yes				
R4011	2009-03-04	Yes				
R4012	2009-03-04	Yes				
R4013	2009-03-04	No	Inclusion	6 Has Dentures, No Regular Dental Check-Ups	Yes	2009-11-19
R4014	2009-03-04	Yes				
R4015	2009-03-04	Yes				
R4016	2009-03-12	Yes				
R4017	2009-03-08	Yes				
R4018	2009-03-10	Yes				
R4019	2009-03-20	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Explanation		
R4020	2009-03-20	Yes				
R4021	2009-03-20	Yes				
R4022	2009-03-26	Yes				
R4023	2009-03-26	Yes				
R4024	2009-03-26	Yes				
R4025	2009-03-20	Yes				
R4026	2009-04-09	Yes				
R4027	2009-04-13	Yes				
R4028	2009-04-16	Yes				
R4029	2009-04-16	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Inclusion/Exclusion Number		
R4030	2009-04-15	Yes				
R4031	2009-04-20	No	Inclusion	6	Yes	2009-11-19
R4032	2009-04-15	Yes				
R4033	2009-04-15	Yes				
R4034	2009-04-15	Yes				
R4035	2009-04-29	Yes				
R4036	2009-04-27	Yes				
R4037	2009-04-28	Yes				
R4038	2009-04-29	Yes				
R4039	2009-04-29	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,				Exemption Granted?	If Yes, Date Granted
			Category	Inclusion/Exclusion Number	Explanation			
R4040	2009-04-29	No	Inclusion	6	Brushes Teeth Twice Daily; No Regular Dental Check-Ups	Yes	2009-11-19	
R4041	2009-04-27	Yes						
R4042	2009-04-29	Yes						
R4043	2009-04-29	Yes						
R4044	2009-04-29	Yes						
R4045	2009-04-28	Yes						
R4046	2009-04-29	No	Inclusion	5	Prostate Cancer, 2004	Yes	2009-05-05	
	2009-04-29	No	Inclusion	6	No Regular Dental Check-Ups, Brushes Teeth Twice A Day	Yes	2009-11-19	
R4047	2009-04-21	Yes						
R4048	2009-04-28	No	Inclusion	6	False Teeth, No Regular Check-Ups	Yes	2009-05-12	

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Inclusion/Exclusion Number		
R4049	2009-04-29	Yes				
R4050	2009-06-02	No	Inclusion	6	False Teeth, Does Not Have Regular Check-Ups	Yes 2009-09-08
R4051	2009-06-02	Yes				
R4052	2009-06-02	Yes				
R4053	2009-06-02	Yes				
R4054	2009-05-26	Yes				
R4055	2009-05-28	Yes				
R4056	2009-05-29	Yes				
R4057	2009-05-27	Yes				
R4058	2009-05-29	No	Inclusion	6	No Regular Dental Check-Ups, Brushes Teeth Twice A Day, Has Dentures	Yes 2009-08-13

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,				Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Inclusion/Exclusion Number	Explanation			
R4059	2009-05-29	Yes						
R4060	2009-05-28	Yes						
R4061	2009-06-10	No	Inclusion	6	No Regular Dental Check-Ups	Yes	2009-11-19	
R4062	2009-06-10	Yes						
R4063	2009-06-10	Yes						
R4064	2009-06-08	No	Inclusion	6	Has Dentures, No Regular Check-Ups	Yes	2009-08-13	
R4065	2009-06-10	Yes						
R4066	2009-06-08	Yes						
R4067	2009-06-08	Yes						
R4068	2009-06-08	No	Inclusion	6	No Regular Check-Ups, Has Dentures	Yes	2009-08-13	

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Number		
R4069	2009-06-10	Yes				
R4070	2009-06-12	Yes				
R4071	2009-06-12	Yes				
R4072	2009-06-12	Yes				
R4073	2009-06-22	Yes				
R4074	2009-06-22	Yes				
R4075	2009-06-22	Yes				
R4076	2009-06-22	Yes				
R4077	2009-06-22	No	Inclusion	6	Brushes Twice Daily, No Regular Dental Check-Ups	Yes 2009-11-19
R4078	2009-06-22	No	Inclusion	6	Last Dental Check-Up 2 Years Ago	Yes 2009-06-30

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Number Explanation		
R4079	2009-06-22	Yes				
R4080	2009-06-22	Yes				
R4081	2009-06-22	Yes				
R4082	2009-06-22	Yes				
R4083	2009-06-08	Yes				
R4084	2009-06-12	Yes				
R4085	2009-06-08	No	Inclusion	6 No Regular Check-Ups, Brushes Daily	Yes	2009-07-02
R4086	2009-06-24	Yes				
R4087	2009-06-24	Yes				
R4088	2009-06-24	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Explanation		
R4089	2009-06-24	Yes				
R4090	2009-06-24	Yes				
R4091	2009-06-22	Yes				
R4092	2009-06-22	Yes				
R4093	2009-05-26	Yes				
R4094	2009-06-26	Yes				
R4095	2009-06-26	Yes				
R4096	2009-06-26	Yes				
R4097	2009-06-26	Yes				
R4098	2009-06-26	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Number		
R4099	2009-06-26	Yes				
R4100	2009-06-26	Yes				
R4101	2009-06-26	Yes				
R4102	2009-06-26	Yes				
R4103	2009-06-26	Yes				
R4104	2009-07-10	No	Exclusion	6	Screening Vs Out Of Range	Yes 2009-07-20
R4105	2009-07-20	Yes				
R4106	2009-07-20	Yes				
R4107	2009-07-20	Yes				
R4108	2009-07-10	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Number Explanation		
R4109	2009-07-17	Yes				
R4110	2009-07-10	Yes				
R4111	2009-07-20	Yes				
R4112	2009-07-17	Yes				
R4113	2009-07-20	Yes				
R4114	2009-07-20	No	Exclusion	6 Vs Out Of Range	Yes	2009-07-23
R4115	2009-07-20	Yes				
R4116	2009-07-20	Yes				
R4117	2009-07-17	Yes				
R4118	2009-07-20	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Explanation		
R4119	2009-07-20	Yes				
R4120	2009-07-20	Yes				
R4121	2009-07-20	Yes				
R5001	2009-06-16	Yes				
R5002	2009-06-16	Yes				
R5003	2009-06-16	Yes				
R5004	2009-06-22	Yes				
R5005	2009-06-23	Yes				
R5006	2009-06-22	Yes				
R5007	2009-06-22	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Explanation		
R5008	2009-06-30	Yes				
R5009	2009-06-29	Yes				
R5010	2009-06-29	Yes				
R5011	2009-06-23	Yes				
R5012	2009-07-06	Yes				
R5013	2009-07-06	Yes				
R5014	2009-07-07	Yes				
R5015	2009-07-06	Yes				
R5016	2009-07-13	Yes				
R5017	2009-07-13	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,		Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Number		
R5018	2009-07-13	Yes				
R5019	2009-07-14	Yes				
R5020	2009-07-14	No	Inclusion	6	Last Dental Check-Up Over 5 Years Ago	Yes 2009-07-21
R5021	2009-07-13	Yes				
R5022	2009-07-20	Yes				
R5023	2009-07-14	Yes				
R5024	2009-07-14	Yes				
R5025	2009-07-21	Yes				
R5026	2009-06-30	No	Inclusion	6	Does Not Have Regular Dental Checkups	Yes 2009-07-23
R5027	2009-07-21	Yes				

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-1 Subject Eligibility

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Study Population: Safety

Subject Number	Informed Consent Date	All Criteria Met?	If No,			Exemption Granted?	If Yes, Date Granted
			Inclusion/Exclusion Category	Inclusion/Exclusion Number	Explanation		
R5028	2009-07-14	Yes					

NOTE: For the criteria definition, see the Protocol.

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R1001	Female	No	White	(b) (6)	64	61.5	158.2	29.5
R1002	Female	No	White	(b) (6)	57	65.0	164.4	27.4
R1003	Female	No	White	(b) (6)	50	63.0	227.2	40.3
R1004	Male	No	White	(b) (6)	59	65.0	149.2	24.9
R1005	Female	No	White	(b) (6)	56	73.0	226.0	29.9
R1006	Female	No	White	(b) (6)	51	67.0	141.2	22.2
R1007	Female	No	White	(b) (6)	49	62.0	112.2	20.6
R1008	Female	No	White	(b) (6)	61	65.0	143.2	23.9
R1009	Female	No	White	(b) (6)	62	66.0	179.0	29.0
R1010	Male	No	Black or African American	(b) (6)	42	69.0	256.2	37.9
R1011	Male	No	White	(b) (6)	54	65.0	208.4	34.8

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R1012	Female	No	White	(b) (6)	50	67.0	128.8	20.2
R1013	Male	No	White	(b) (6)	47	74.0	221.2	28.5
R1014	Female	No	White	(b) (6)	53	60.0	133.4	26.1
R1015	Female	No	White	(b) (6)	40	63.0	127.6	22.7
R1016	Male	Yes	Other: Taino Indian	(b) (6)	25	68.9	222.6	33.0
R1017	Female	No	White	(b) (6)	47	62.0	115.8	21.2
R1018	Female	No	White	(b) (6)	43	67.5	180.4	27.9
R1019	Male	No	White	(b) (6)	42	65.0	143.0	23.8
R1020	Male	No	White	(b) (6)	27	66.0	239.8	38.8
R1021	Female	No	White	(b) (6)	33	64.0	211.2	36.3
R1022	Female	No	White	(b) (6)	33	63.6	202.2	35.2

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R1023	Male	No	White	(b) (6)	48	67.1	196.6	30.8
R1024	Female	No	White	(b) (6)	38	63.5	157.2	27.5
R1025	Female	No	White	(b) (6)	46	62.8	141.8	25.3
R1026	Female	No	White	(b) (6)	41	61.0	159.4	30.2
R1027	Female	No	White	(b) (6)	64	63.0	152.0	27.0
R1028	Female	No	White	(b) (6)	42	63.8	151.2	26.2
R1029	Female	No	White	(b) (6)	34	63.5	220.0	38.4
R1030	Female	No	White	(b) (6)	62	66.0	238.8	38.6
R1031	Female	No	White	(b) (6)	63	64.0	154.2	26.5
R1032	Female	No	White	(b) (6)	35	69.0	215.6	31.9
R1033	Female	No	White	(b) (6)	40	61.0	161.4	30.6

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R1034	Male	No	Black or African American	(b) (6)	56	71.0	179.6	25.1
R1035	Male	No	White	(b) (6)	58	70.5	195.4	27.7
R1036	Female	No	White	(b) (6)	44	66.0	201.4	32.6
R1037	Male	No	White	(b) (6)	62	66.5	208.6	33.2
R2001	Male	No	White	(b) (6)	30	69.0	159.8	23.6
R2002	Female	No	White	(b) (6)	34	68.3	120.4	18.2
R2003	Female	No	White	(b) (6) (b)	38	62.9	155.8	27.7
R2004	Female	No	White	(b) (6)	53	62.1	285.8	52.2
R2005	Male	No	White	(b) (6)	44	66.4	210.4	33.6
R2006	Female	No	White	(b) (6)	38	63.9	124.2	21.4
R2007	Male	No	White	(b) (6) (b)	55	68.0	192.8	29.4

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R2008	Female	No	White	(b) (6)	32	64.7	153.6	25.9
R2009	Male	No	White	(b) (6)	28	71.1	146.0	20.3
R2010	Female	No	White	(b) (6)	48	65.5	279.4	45.9
R2011	Female	No	White	(b) (6)	51	68.0	149.6	22.8
R2012	Female	No	White	(b) (6)	53	63.0	129.6	23.0
R2013	Female	No	Black or African American	(b) (6)	46	63.5	135.8	23.7
R2014	Female	No	White	(b) (6)	46	63.7	145.0	25.2
R2015	Female	No	White	(b) (6)	32	62.1	189.6	34.6
R2016	Male	No	White	(b) (6)	60	71.1	254.8	35.5
R2017	Female	No	Other: American Indian or Alaskan Native, White	(b) (6)	47	66.3	201.6	32.3
R2018	Male	No	White	(b) (6)	46	69.9	220.0	31.7

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R2019	Male	No	White	(b) (6)	28	76.6	382.2	45.9
R2020	Male	No	White	(b) (6)	29	71.5	148.6	20.5
R2021	Female	No	Black or African American	(b) (6)	57	62.1	205.2	37.5
R2022	Female	No	White	(b) (6)	48	67.3	163.6	25.4
R2023	Female	No	White	(b) (6)	30	66.8	159.2	25.1
R2024	Male	No	White	(b) (6)	31	73.3	181.0	23.7
R2025	Male	No	White	(b) (6)	29	71.3	172.0	23.8
R2026	Female	No	White	(b) (6)	57	63.8	182.8	31.6
R2027	Female	No	White	(b) (6)	60	67.1	202.6	31.7
R2028	Female	No	White	(b) (6)	42	71.5	231.2	31.9
R2029	Female	No	White	(b) (6)	61	64.7	144.0	24.2

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R2030	Male	Yes	White	(b) (6)	64	68.4	186.6	28.1
R2031	Female	No	White	(b) (6)	29	64.1	138.0	23.7
R2032	Female	No	White	(b) (6)	26	62.3	108.4	19.7
R3001	Female	No	White	(b) (6)	29	63.6	135.2	23.5
R3002	Female	No	White	(b) (6)	57	63.3	209.9	36.9
R3003	Male	No	White	(b) (6)	50	69.9	180.4	26.0
R3004	Male	No	White	(b) (6)	28	71.9	118.8	16.2
R3005	Female	No	White	(b) (6)	59	65.2	165.6	27.4
R3006	Female	No	White	(b) (6)	62	65.5	170.2	28.0
R3007	Male	No	Other: White-Arabic/North African Heritage	(b) (6)	33	70.6	129.8	18.3
R3008	Male	No	White	(b) (6)	39	72.5	160.0	21.4

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R3009	Female	No	White	(b) (6)	63	58.5	120.0	24.7
R3010	Female	No	White	(b) (6)	33	64.6	197.4	33.3
R3011	Female	No	White	(b) (6)	44	52.8	262.4	66.3
R3012	Male	No	White	(b) (6)	48	68.5	193.0	29.0
R3013	Male	No	White	(b) (6)	36	71.0	204.0	28.5
R3014	Female	No	White	(b) (6)	47	66.0	147.1	23.8
R3015	Female	No	White	(b) (6)	43	59.9	169.0	33.2
R3016	Female	No	White	(b) (6)	48	69.9	158.2	22.8
R3017	Female	No	White	(b) (6)	30	67.0	118.3	18.6
R3018	Male	No	White	(b) (6)	39	80.5	289.8	31.5
R3019	Female	No	White	(b) (6)	50	67.1	166.2	26.0

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R3020	Male	No	White	(b) (6)	41	72.8	242.2	32.2
R3021	Male	No	Other: White And American Indian/Alaskan Native	(b) (6)	53	65.5	153.0	25.1
R3022	Male	No	White	(b) (6)	33	72.9	368.6	48.9
R3023	Female	No	White	(b) (6)	62	61.5	165.6	30.8
R3024	Male	No	White	(b) (6)	50	71.0	232.4	32.5
R3025	Female	No	White	(b) (6)	38	63.3	246.8	43.4
R3026	Male	No	White	(b) (6)	31	74.0	232.8	30.0
R3027	Female	No	Other: White/Native Hawaiian or Other Pacific Islander	(b) (6)	29	60.5	142.6	27.4
R3028	Female	No	Black or African American	(b) (6)	39	65.9	238.2	38.6
R3029	Female	No	White	(b) (6)	64	65.7	177.0	28.9
R3030	Male	No	White	(b) (6)	32	67.0	166.6	26.1

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R3031	Female	No	White	(b) (6)	39	66.0	161.2	26.1
R3032	Female	No	White	(b) (6)	54	70.0	260.0	37.4
R4001	Male	No	White	(b) (6)	50	67.9	229.0	35.0
R4002	Female	No	White	(b) (6)	57	67.0	146.0	22.9
R4003	Male	No	White	(b) (6)	63	72.0	224.6	30.5
R4004	Female	No	White	(b) (6)	30	68.5	157.6	23.7
R4005	Male	No	White	(b) (6)	41	67.5	177.6	27.5
R4006	Female	No	White	(b) (6)	36	64.5	168.2	28.5
R4007	Female	No	White	(b) (6)	37	63.7	121.0	21.0
R4008	Female	No	White	(b) (6)	51	64.5	177.2	30.0
R4009	Female	No	White	(b) (6)	29	64.3	133.8	22.8

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R4010	Female	No	White	(b) (6)	50	66.6	126.0	20.0
R4011	Female	No	White	(b) (6)	47	60.6		
R4012	Female	No	White	(b) (6)	53	63.6	130.6	22.7
R4013	Female	No	White	(b) (6)	52	61.6	193.2	35.9
R4014	Female	No	White	(b) (6)	31	66.5	114.4	18.2
R4015	Female	No	White	(b) (6)	57	62.8	119.4	21.3
R4016	Male	No	White	(b) (6)	28	66.5	172.6	27.5
R4017	Female	No	White	(b) (6)	49	60.0	205.0	40.1
R4018	Female	No	White	(b) (6)	27	68.3	167.0	25.2
R4019	Female	No	White	(b) (6)	43	65.1	172.4	28.7
R4020	Male	No	White	(b) (6)	40	71.0	171.8	24.0

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R4021	Female	No	White	(b) (6)	52	65.2	134.2	22.2
R4022	Female	No	White	(b) (6)	27	64.5	147.8	25.0
R4023	Female	No	White	(b) (6)	51	59.5	116.4	23.2
R4024	Male	No	Other: White And American Indian or Alaskan Native	(b) (6)	30	70.5	325.0	46.1
R4025	Male	No	White	(b) (6)	54	68.2	213.6	32.4
R4026	Male	No	White	(b) (6)	60	68.9	175.0	26.0
R4027	Male	No	White	(b) (6)	44	73.3	233.2	30.6
R4028	Female	No	White	(b) (6)	49	63.5	162.2	28.3
R4029	Male	No	White	(b) (6)	48	66.4	242.4	38.7
R4030	Male	No	Black or African American	(b) (6)	47	72.0	164.0	22.3
R4031	Female	No	White	(b) (6)	50	76.0	198.2	24.2

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R4032	Female	No	White	(b) (6)	33	67.0	241.8	38.0
R4033	Female	No	White	(b) (6)	49	63.2	141.6	25.0
R4034	Male	No	White	(b) (6)	45	69.7	192.2	27.9
R4035	Female	No	White	(b) (6)	45	70.7	183.8	25.9
R4036	Male	No	White	(b) (6)	31	73.8	241.4	31.2
R4037	Male	No	American Indian or Alaska Native	(b) (6)	43	72.5	157.2	21.1
R4038	Male	No	White	(b) (6)	58	71.2	176.8	24.6
R4039	Female	No	White	(b) (6)	60	63.4	152.2	26.7
R4040	Female	No	White	(b) (6)	59	67.7	236.2	36.3
R4041	Female	No	White	(b) (6)	55	61.5	134.6	25.1
R4042	Male	No	White	(b) (6)	58	66.7	136.0	21.5

Listing 16.2.4-2 Screening Demographics by Subject

Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R4043	Female	No	White	(b) (6)	55	63.3	180.8	31.8
R4044	Female	No	Black or African American	(b) (6)	29	67.0	307.0	48.2
R4045	Female	No	White	(b) (6)	45	68.4	156.6	23.6
R4046	Male	No	White	(b) (6)	57	71.6	140.8	19.4
R4047	Male	No	White	(b) (6)	47	67.6	173.4	26.7
R4048	Female	No	White	(b) (6)	60	64.4	184.0	31.3
R4049	Female	No	White	(b) ((b)	40	63.5	158.2	27.6
R4050	Female	No	White	(b) (6)	50	61.5	231.4	43.1
R4051	Male	No	White	(b) (6)	50	70.6	252.0	35.6
R4052	Male	No	White	(b) (6)	63	66.2	136.2	21.9
R4053	Female	No	White	(b) (6)	38	65.5	186.9	30.7

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R4054	Male	No	White	(b) (6)	44	70.8	193.8	27.2
R4055	Male	No	White	(b) (6)	31	69.0	206.4	30.5
R4056	Female	No	White	(b) (6)	47	67.2	185.4	28.9
R4057	Female	No	White	(b) (6)	49	68.0	250.6	38.2
R4058	Female	No	White	(b) (6)	55	63.5	121.7	21.3
R4059	Male	No	White	(b) (6)	56	71.2	209.0	29.0
R4060	Male	No	White	(b) (6)	55	69.0	189.4	28.0
R4061	Female	No	White	(b) (6)	51	64.7	188.0	31.6
R4062	Male	No	Black or African American	(b) (6) (b)	44	69.8	228.6	33.1
R4063	Male	No	White	(b) (6)	58	70.5	199.6	28.3
R4064	Male	No	White	(b) (6)	49	68.8	168.8	25.1

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R4065	Female	No	White	(b) (6)	27	64.8	190.8	32.0
R4066	Female	No	White	(b) (6)	51	62.9	185.8	33.1
R4067	Female	No	White	(b) (6)	45	63.5	194.8	34.0
R4068	Female	No	White	(b) (6)	46	62.5	161.6	29.1
R4069	Male	No	White	(b) (6)	55	72.6	202.2	27.0
R4070	Male	No	White	(b) (6)	28	69.0	227.0	33.6
R4071	Male	No	White	(b) (6)	25	66.4	174.6	27.9
R4072	Male	No	White	(b) (6)	49	75.3	171.8	21.3
R4073	Female	No	White	(b) (6)	55	69.4	171.4	25.1
R4074	Male	No	White	(b) (6)	28	67.2	183.4	28.6
R4075	Male	No	White	(b) (6)	35	68.5	176.8	26.5

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R4076	Female	No	White	(b) (6)	38	65.6	172.4	28.2
R4077	Female	No	Black or African American	(b) (6)	41	64.7	188.0	31.6
R4078	Male	No	White	(b) (6)	42	71.6	229.0	31.5
R4079	Female	No	White	(b) (6)	29	62.4	174.2	31.5
R4080	Male	No	White	(b) (6)	34	70.2	195.2	27.9
R4081	Female	No	White	(b) (6)	62	61.6	117.6	21.8
R4082	Male	No	White	(b) (6)	51	67.2	157.4	24.6
R4083	Male	No	Other: White, American Indian/Alaskan Native	(b) (6)	55	65.1	140.4	23.3
R4084	Female	No	White	(b) (6)	44	65.5	223.6	36.7
R4085	Male	No	White	(b) (6)	37	73.2	245.8	32.3
R4086	Female	No	White	(b) (6)	61	64.1	159.0	27.3

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R4087	Female	No	White	(b) (6)	63	62.8	132.6	23.7
R4088	Female	No	White	(b) (6)	26	65.2	233.8	38.7
R4089	Male	No	White	(b) (6)	52	68.9	198.2	29.4
R4090	Female	No	White	(b) (6)	47	64.8	130.4	21.9
R4091	Female	No	White	(b) (6)	30	66.6	229.0	36.4
R4092	Male	No	White	(b) (6)	49	63.6	164.2	28.6
R4093	Male	No	White	(b) (6)	50	77.8	198.0	23.0
R4094	Female	No	Native Hawaiian or Other Pacific Islander	(b) (6)	53	63.1	139.5	24.7
R4095	Male	No	White	(b) (6)	34	67.0	200.4	31.5
R4096	Female	No	White	(b) (6)	25	64.3	141.8	24.2
R4097	Male	No	White	(b) (6)	63	73.0	171.8	22.7

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R4098	Female	No	White	(b) (6)	28	60.6	101.8	19.5
R4099	Male	No	White	(b) (6)	27	68.2	237.4	36.0
R4100	Male	No	White	(b) (6)	39	70.1	183.4	26.3
R4101	Male	No	White	(b) (6)	26	70.6	147.2	20.8
R4102	Female	No	Black or African American	(b) (6)	46	65.6	159.8	26.2
R4103	Male	No	White	(b) (6)	27	68.5	147.8	22.2
R4104	Male	No	White	(b) (6)	44	70.9	169.8	23.8
R4105	Male	No	White	(b) (6)	53	67.5	156.8	24.2
R4106	Male	No	Black or African American	(b) (6)	42	71.7	225.0	30.8
R4107	Female	No	White	(b) (6)	41	65.2	255.2	42.3
R4108	Male	No	White	(b) (6)	32	73.9	299.8	38.7

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R4109	Male	No	White	(b) (6)	44	65.6	153.0	25.0
R4110	Female	No	White	(b) (6)	41	65.4	132.2	21.8
R4111	Female	No	Black or African American	(b) (6)	33	61.6	164.8	30.6
R4112	Female	No	White	(b) (6)	28	69.5	183.6	26.8
R4113	Female	No	White	(b) (6)	36	67.7	211.2	32.5
R4114	Female	No	White	(b) (6)	61	65.4	209.0	34.4
R4115	Male	No	White	(b) (6)	42	68.1	202.6	30.8
R4116	Male	No	White	(b) (6)	61	68.9	168.0	24.9
R4117	Female	No	White	(b) (6)	46	64.5	196.8	33.3
R4118	Female	No	White	(b) (6)	30	64.1	231.0	39.6
R4119	Female	No	Black or African American	(b) (6)	42	68.1	195.2	29.7

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R4120	Female	No	White	(b) (6)	49	64.5	147.0	24.9
R4121	Female	No	White	(b) (6)	31	64.3	144.4	24.6
R5001	Male	No	White	(b) (6)	47	67.5	195.0	30.2
R5002	Female	No	White	(b) (6)	31	65.8	275.6	44.8
R5003	Male	No	Black or African American	(b) (6)	50	71.5	301.6	41.6
R5004	Female	No	American Indian or Alaska Native	(b) (6)	33	66.3	205.4	32.9
R5005	Female	No	Black or African American	(b) (6)	52	66.0	247.8	40.1
R5006	Female	No	White	(b) (6)	50	64.0	128.0	22.0
R5007	Male	No	White	(b) (6)	40	71.0	302.2	42.2
R5008	Female	No	White	(b) (6)	54	66.0	224.4	36.3
R5009	Male	No	White	(b) (6)	42	68.3	203.0	30.7

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R5010	Female	No	White	(b) (6)	58	69.6	215.0	31.3
R5011	Female	Yes	White	(b) (6)	49	63.0	191.4	34.0
R5012	Female	No	White	(b) (6)	56	64.0	131.2	22.6
R5013	Female	No	White	(b) (6)	51	61.5	124.4	23.2
R5014	Male	No	Black or African American	(b) (6)	46	69.5	233.2	34.0
R5015	Female	No	White	(b) (6)	61	61.5	108.6	20.2
R5016	Female	No	White	(b) (6)	56	60.7	139.0	26.6
R5017	Female	No	Black or African American	(b) (6)	58	62.0	215.8	39.6
R5018	Male	No	Black or African American	(b) (6)	51	70.2	198.6	28.4
R5019	Male	No	White	(b) (6)	44	70.0	203.6	29.3
R5020	Female	No	White	(b) (6)	62	66.9	192.6	30.3

Listing 16.2.4-2 Screening Demographics by Subject

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Study Population: ITT

Subject Number	Gender	Ethnicity Hispanic or Latino?	Race	Date of Birth	Age (years)	Height (cm)	Weight (kg)	BMI (kg/m ²)
R5021	Female	Yes	White	(b) (6)	33	61.1	128.0	24.2
R5022	Female	No	White	(b) (6)	38	62.5	144.2	26.0
R5023	Female	No	White	(b) (6)	48	64.8	133.2	22.3
R5024	Female	No	White	(b) (6)	37	70.0	186.0	26.7
R5025	Male	Yes	White	(b) (6)	57	70.6	168.0	23.7
R5026	Male	No	White	(b) (6)	45	68.8	147.2	21.9
R5027	Female	No	White	(b) (6)	34	67.8	167.8	25.7
R5028	Female	No	White	(b) (6)	52	66.3	183.0	29.3

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R1001	Hypothyroidism	1996	ONGOING
	Postmenopausal	1986-05-26	ONGOING
R1002	Cataracts	2009-02-18	ONGOING
	Hot Flashes	2004	ONGOING
	Hypertension	2007	ONGOING
	Osteoarthritis (C-Spine, Knees)	2005	ONGOING
	Pollen Allergies	2002	ONGOING
	Postmenopausal	2006-10	ONGOING
R1003	Hemorrhoids	1998	ONGOING
	High Blood Pressure	1989	ONGOING
	Intermittent Episodes-Folliculitis/Abscesses Or Boils (Inner Thighs & Private Area)	1976	ONGOING
	Intermittent Episodes-Numbness/Tingling (Extremities)	2007	ONGOING
	Intermittent Nasal/Sinus Congestion	1975	ONGOING
	Postmenopausal	2007-09	ONGOING
	Recurrent Back Pain	2006	ONGOING
	Seasonal Allergies	1989	ONGOING
R1004	Partial Upper Dentures	2009-03-02	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R1005	High Cholesterol	2008	ONGOING
	Osteoarthritis-Hands	2007	ONGOING
	Seasonal Allergies	2000	ONGOING
	Tubal Ligation	1975	1975
R1006	Postmenopausal	2005	ONGOING
R1007	Menopause	2005	ONGOING
R1008	Anxiety/Panic Attacks	1999	ONGOING
	Asthma	2004	ONGOING
	Borderline Hypertension	2008-12-04	ONGOING
	Chronic Cough	2000	ONGOING
	Cold Sores, Herpes Simplex	2000	ONGOING
	Depression	1999	ONGOING
	Heartburn	2008	ONGOING
	Hemorrhoids	1974	ONGOING
	Hysterectomy	1986	1986
Insomnia	1970	ONGOING	

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R1008	Osteoarthritis-Left Shoulder	2000	ONGOING
	Recurrent Joint Pain-Bursitis Left Shoulder	2004	ONGOING
	Shortness Of Breath Upon Exertion	2007	ONGOING
R1009	Hypertension	1997	ONGOING
	Hysterectomy	1997	1997
	Root Canal Tooth #19	(b) (6)	(b) (6)
	Shortness Of Breath Upon Exertion	2000	ONGOING
R1011	Acid Reflux	1973	ONGOING
	Heartburn	1973	ONGOING
	Hypertension	2006	ONGOING
	Occasional Headaches	1964	ONGOING
	Seasonal Allergies	1999	ONGOING
R1012	Headache	2009-03-29	2009-03-29
	Occasional Body Aches	2004	ONGOING
	Occasional Leg Cramps	1970	ONGOING
	Postmenopausal	2005-03	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R1013	Allergic To Oak Pollen	2008-04	ONGOING
R1014	Edentulous	1984	ONGOING
	Heartburn	2007	ONGOING
	Hot Flashes	2007	ONGOING
	Postmenopausal	2003-10-09	ONGOING
	Psoriasis	1976	ONGOING
	Recurrent Back Pain (Lower Back)	2007	ONGOING
	Shortness Of Breath Upon Exertion	2008-11-12	ONGOING
R1015	Penicillin Allergy	1981	ONGOING
	Seasonal Allergies	1972	ONGOING
R1019	Recurrent Back Pain	1987	ONGOING
	Shortness Of Breath Upon Exertion	1999	ONGOING
R1020	Periodically Nasal/Sinus Congestion	2000	ONGOING
	Recurrent Back Pain	2002	ONGOING
	Recurrent Joint Pain (Bilateral Knees)	2002	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R1020	Shortness Of Breath Upon Exertion	2002	ONGOING
R1021	Low Back Pain	2001-05	ONGOING
R1022	Menstrual Cramps Tubal Ligation	1999 1997-04	ONGOING 1997-04
R1023	Headaches	1975	ONGOING
R1024	Acne Chronic Bronchitis Chronic Cough Dentures Full Set Tinea Corporis	1999 1998 2001 2007 2009-06-22	ONGOING ONGOING ONGOING ONGOING 2009-08-22
R1025	Blue Surgical Dye Allergies Hysterectomy Left Breast Cancer(Lumpectomy) Leg Cramps-Occasionally At Night	2002 2006-11 2002-10 1995	ONGOING 2006-11 2003-05 ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R1025	Nose Bleeds	1966	ONGOING
	Osteopenia	2008	ONGOING
	Scoliosis	2002	ONGOING
	Wellbutrin Allergies	1977	ONGOING
R1026	Tubal Ligation	1988-10	1988-10
R1027	Hemorrhoids	1963	ONGOING
	Hypertension	2007	ONGOING
	Penicillin Allergy	1961	ONGOING
	Post Menopausal	1994-12	ONGOING
	Shortness Of Breath Upon Exertion	2006	ONGOING
R1028	Heartburn	1989	ONGOING
	Leg Cramps-Occasionally	2007	ONGOING
	Tubal Ligation	(b) (6)	(b) (6)
	Upper Dentures	2007	ONGOING
R1029	Cold Sores/Herpes Simplex	2001	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R1029	Heartburn	1996	ONGOING
	Hidradenitis Suppurativa	2006	ONGOING
	Insomnia	2001	ONGOING
	Rosacea	2005	ONGOING
R1030	Chronic Cough	2004	ONGOING
	Continuous Chronic Semi-Numbness & Occasional Tingling In Middle Toes (Bilaterally)	1997	ONGOING
	Diabetes (Type 2)	2008-07	ONGOING
	Herpes Simplex	1978	ONGOING
	High Blood Pressure	2000	ONGOING
	High Cholesterol	2000	ONGOING
	Hysterectomy	1995	1995
	Osteoarthritis (Left Hip And Back)	2000	ONGOING
Recurrent Back Pain	1983	ONGOING	
R1031	Basal Cell Carcinoma	1995	1995
	Nasal/Sinus Congestion-Occasionally	1960	ONGOING
	Osteoarthritis	1995	ONGOING
	Post-Menopausal	2000	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R1031	Right Hip Pain	1969	ONGOING
	Sinus Infections	1960	ONGOING
R1032	Acne	2002	ONGOING
	Recurrent Joint Pain	1996	ONGOING
R1033	Migraine Headaches	1983	ONGOING
	Tension Headaches	1992	ONGOING
	Tubal Ligation	(b) (6)	(b) (6)
R1034	Bladder Control Problems	2007	ONGOING
	Eczema (Bilateral Hands And Feet)	1976	ONGOING
	Hypertension	2007	ONGOING
	Recurrent Joint Pain (Bilateral Knees, Ankles, Right Wrist)	2008	ONGOING
	Reducible Ventrial Hernia	UNK	ONGOING
	Upper And Lower Dentures	1989	ONGOING
R1035	Episodic Dizziness/Lightheadedness (Large Amounts Of Blood Drawn)	1972	ONGOING
	Hearing Loss	1982	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R1035	Heartburn	1995	ONGOING
	High Triglycerides	2006	ONGOING
	Hypercholesterolemia	1999	ONGOING
	Left Elbow Pain	2003	ONGOING
	Low Back Pain	1970	ONGOING
R1036	Dentures	1992	ONGOING
	Depression	1973	ONGOING
	Headaches (Tension/Stress)	2009	ONGOING
	Hearing Loss	1970	ONGOING
	Incontinence/Bladder Control Problems	1968	ONGOING
	Recurrent Joint Pain (Right Shoulder)	2004	ONGOING
	Shortness Of Breath Upon Exertion	1989	ONGOING
	Tubal Ligation	(b) (6)	(b) (6)
R1037	Allergic To Penicillin	1948-01-01	ONGOING
	Allergies To Cats	1948-01-01	ONGOING
	Benign Prostatic Hypertrophy	2004-01-01	ONGOING
	Diabetes-Type 2	2007-01-01	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R1037	Hayfever	1948-01-01	ONGOING
	Hypercholesterolemia	2004-01-01	ONGOING
	Recurrent Back Pain	2008-01-01	ONGOING
R2001	Muscle Aches And Inflammation In Both Legs	2009-02	2009-02
R2002	Migraines	2002	ONGOING
	Mild To Moderate Acne Related To Menses	1999	ONGOING
	Nasal/Sinus Congestion	2008	ONGOING
R2003	Depression	2003	ONGOING
	Insomnia	2008	2009-05
	Migraines	1998	ONGOING
	Mild Asthma	1998	ONGOING
	Ovarian Cysts	1984	ONGOING
	Seasonal/Environmental Allergies	1988	ONGOING
R2004	Chronic Throat Infections	1989	ONGOING
	Constipation	2009	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R2004	Mild Asthma	1989	ONGOING
	Seasonal Allergies	1975	ONGOING
	Sinusitis	1975	ONGOING
R2006	Mild Cold	2009-02	2009-03-07
	Mild Constipation	2009-03	2009-03
	Pharyngitis	2009-03-19	2009-03-28
R2007	Mild Heartburn	1969	ONGOING
	Shortness Of Breath Related To Smoking Cigarettes	2003	ONGOING
	Shortness Of Breath Upon Exertion During Mild Strenuous Activity	2005	ONGOING
	Sinus Headaches	1970	ONGOING
R2008	Bronchitis	2009-04-17	2009-04-24
	Menstrual Cramps Episodic/Intermittent	1997	ONGOING
R2010	Anemia	1981	ONGOING
	Diabetes Type Ii	1995	ONGOING
	Diabetic Neuropathy	2004-02	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R2010	Gastroesophageal Reflux Disease	1985	ONGOING
	Heartburn	1985	ONGOING
	High Blood Pressure	1994	ONGOING
	Increased Heart Rate	2006	ONGOING
	Nasal/Sinus Congestion Episodic/Intermittent	1971	ONGOING
	Respiratory Bronchial Interstitial	2000	ONGOING
	Seasonal Allergies	1999	ONGOING
	Shortness Of Breath When Walking	2000	ONGOING
R2011	General Aches And Pain	1976	ONGOING
	Seasonal Allergies	2000	ONGOING
	Sinus Infections	2000	ONGOING
	Tension Headaches	1985	ONGOING
R2012	General Aches	1989	ONGOING
	Nasal/Sinus Congestion Episodic/Intermittent	1989	ONGOING
	Seasonal Allergies	1989	ONGOING
	Tension Headaches	2005	ONGOING
R2013	General Aches And Pains	1979	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R2013	Nasal/Sinus Congestion	2005	ONGOING
	Recurrent Back Pain	1997	ONGOING
	Seasonal Allergies	2005	ONGOING
	Sinus Headaches	2004	ONGOING
	Sinus Infections	2005	ONGOING
R2014	Hysterectomy	2004	2004
	Tension Headaches	1981	ONGOING
R2015	Chronic Cough	2004	ONGOING
	Nasal/Sinus Congestion Episodic/Intermittent	1995	ONGOING
	Recurrent Back Pain	2005	ONGOING
	Seasonal Allergies	1995	ONGOING
	Shortness Of Breath Due To Smoking	1991	ONGOING
	Shortness Of Breath Upon Exertion Due To Strenuous Activity	1991	ONGOING
	Sinus Infections	1995	ONGOING
Tension Headaches	1994	ONGOING	
R2016	High Blood Pressure	2008	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R2016	High Cholesterol	2008	ONGOING
	Osteoarthritis	2009	ONGOING
	Shortness Of Breath Upon Exertion Due To Strenuous Activity	2006	ONGOING
R2017	Heart Murmur	1961	ONGOING
	Irritable Bowel Syndrome Moderate	2007	ONGOING
	Mild Rosacea	1974	ONGOING
	Partial Hysterectomy	2005	2005
	Tension Headaches	1981	ONGOING
R2018	Hernia	2007	ONGOING
R2019	Mild Asthma	1984	ONGOING
	Osteoarthritis Right Shoulder	2009	ONGOING
	Seasonal Allergies	1988	ONGOING
	Tension Headaches	1990	ONGOING
R2020	Shortness Of Breath Upon Exertion Due To Strenuous Exercise	1998	ONGOING
R2021	Gastroesophageal Reflux Disease	2007	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R2021	Hyperlipidemia	2009	ONGOING
	Osteoporosis/Osteopenia	2009	ONGOING
	Seasonal Allergies	2004	ONGOING
	Tension Headaches	1989	ONGOING
	Tubal Ligation	2002	2002
R2022	Occasional Urinary Tract Infection	1978	ONGOING
R2023	Goiter	2005	ONGOING
	Hypothyroidism	2005	ONGOING
	Mild Migraines	2004	ONGOING
	Mild Shortness Of Breath Upon Exertion	2003	ONGOING
	Seasonal Allergies	2004	ONGOING
R2024	Asthma	1984	ONGOING
	Mild Shortness Of Breath Upon Exertion	2006	ONGOING
	Seasonal Allergies	2004	ONGOING
R2025	General Aches And Pain	1995	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R2025	Poison Ivy Rash	2009-07-11	2009-07-17
	Shortness Of Breath Upon Exertion	2002	ONGOING
	Tension Headaches	1994	ONGOING
R2026	Fibromyalgia	1999	ONGOING
	High Cholesterol	1994	ONGOING
	Mild Hypopigmentation Bilateral Dorsal Hands	1994	ONGOING
	Toothaches Due To Upper Incisors Periodontal Disease	1983	2003
	Tubal Ligation	(b) (6)	((b) (6) b
R2027	Herniated Discs Back	1998	ONGOING
	Hysterectomy	2003-02	2003-02
	Numbness/Tingling Right Lower Extremity Episodic/Intermittent	1998	ONGOING
	Occasional Headaches	1964	ONGOING
	Shortness Of Breath Upon Exertion	1962	ONGOING
R2028	Occasional Mild Headaches	1984	ONGOING
	Tubal Ligation	(b) (6)	((b) (6))
R2029	Diabetes Type Ii	2008	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R2029	High Blood Pressure	2006	ONGOING
	High Cholesterol	2008	ONGOING
	Postmenopausal	1996	ONGOING
	Seasonal Allergies	1999	ONGOING
R2030	Leg Cramps Moderate Episodic/Intermittent	1980	ONGOING
R2031	Mild Headaches	1992	ONGOING
	Tubal Ligation	(b) (6)	(b) (6)
R2032	Mild Headaches	2000	ONGOING
R3001	Recurrent Back Pain - Vehicle Accident	1989	ONGOING
R3002	Headaches-Tension	1960	ONGOING
	Hot Flashes-Occasional	2004	ONGOING
	Hypothyroidism	1983	ONGOING
	Hysterectomy	1989	1989
	Leg Cramps-Secondary To Hypothyroidism	1983	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R3002	Restless Leg Syndrome	2007-01	ONGOING
R3003	Common Cold	2009-02-21	2009-02-27
	Headaches-Stress/Tension	1976	ONGOING
	Hemorrhoids	2005	ONGOING
	Recurrent Joint Pain Left Knee	1982	ONGOING
	Seasonal Allergies-Hayfever	1991	ONGOING
R3004	Acne	1992	ONGOING
	Gastroesophageal Reflux Disease	2004	ONGOING
	Heartburn	2004	ONGOING
R3005	High Cholesterol	2005	ONGOING
	Swelling In Right Hand	2008	ONGOING
R3006	Aches Bilateral Shoulders	1962	ONGOING
	Allergy-Dust	2009-01	ONGOING
	Allergy-Seasonal/Pollen	1958	ONGOING
	Chronic Constipation	1975	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R3006	Cold Sores, Herpes Simplex	1982	ONGOING
	Depression-Seasonal	1984	ONGOING
	Headaches-Eyestrain	1962	ONGOING
	Headaches-Head Injury	2007	ONGOING
	Heart Murmur	2000	ONGOING
	High Blood Pressure	2000	ONGOING
	High Cholesterol	2000	ONGOING
	Insomnia	2008	ONGOING
	Nasal/Sinus Congestion Due To Allergies	1958	ONGOING
	Occasional Dizziness/Lightheadedness	2000	ONGOING
R3007	Headaches	1999	ONGOING
	Heartburn	1999	ONGOING
R3008	Depression (No Medication)	1981	ONGOING
	Heat Rash (Occasionally)	2006	ONGOING
	Hemorrhoids	2008	ONGOING
R3009	Chronic Cough	1999	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R3009	Gerd	1999	2006
	Insomnia	1965	ONGOING
	Osteoporosis	2001	ONGOING
	Tension Headaches	1963	ONGOING
R3010	Headaches-Rarely	1985	ONGOING
	High Blood Pressure	2008-08	ONGOING
	Recurrent Back Pain Herniated Disc	1995	ONGOING
R3011	Anxiety	1988	ONGOING
	Gastroesophageal Reflux	1984	ONGOING
	Headaches - Tension	2004	ONGOING
	Heartburn	1984	ONGOING
	Seasonal Allergies	1976	ONGOING
R3012	Erectile Dysfunction	2004	ONGOING
	Headaches-2 Times A Month	1999	ONGOING
R3013	Joint Pain Knee - Bilateral	1986	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R3013	Migraines	1997	ONGOING
	Photophobia	1993	ONGOING
R3014	Rosacea	1995	ONGOING
	Scoliosis	1975	ONGOING
	Tubal Ligation	1985	1985
R3015	Blotchy Cool Hands	2009-03	ONGOING
	Fair Skin With Lesions	2009-03	ONGOING
	Headaches	1987	ONGOING
	Leg Cramps Intermittent/ With Monthly Cycle	1975	ONGOING
	Menstrual Cramps	1975	ONGOING
	Rare Rhonchi With Deep Breath	2009-03	ONGOING
	Tubal Ligation	(b) (6)	(b) (6)
R3017	Upper Respiratory Tract Infection	2009-03	2009-04-09
R3018	Eczema Right Hand	1987	ONGOING
	Tooth Decay	UNK	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R3019	Minor Hearing Loss Right Ear	1962	ONGOING
	Osteoarthritis-Hands	2007	ONGOING
	Recurrent Joint Pain Bilateral Hands	2007	ONGOING
R3020	Borderline High Cholesterol	2008	ONGOING
	Headaches	1990	ONGOING
	Hernia Groin (Type Unknown)	2008-01	ONGOING
	Migraines	1986	ONGOING
	Occasional Heartburn	2000	ONGOING
R3022	Bilateral Leg Edema	2004	ONGOING
	Central Obesity	2009-04-30	ONGOING
	Codeine Allergy	1980	ONGOING
	High Cholesterol	1995	ONGOING
	Seasonal Allergies	1994	ONGOING
	Shellfish Allergy	1983	ONGOING
R3023	Borderline High Blood Pressure	2007	ONGOING
	Fibroid Uterus	1990	1990

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R3023	Heart Murmur	1961	ONGOING
	High Cholesterol	2008	ONGOING
	Hysterectomy	1990	1990
	Mild Stress Incontinence	1989	ONGOING
R3024	Heartburn	1994	ONGOING
	Shortness Of Breath Upon Exertion	2007	ONGOING
	Tension Headache Intermittent (About 1 Per Month)	1994	ONGOING
R3025	Dizziness/Lightheadedness Due To Low Blood Sugar	1998	ONGOING
	Hot Flashes	2009-03	ONGOING
	Menstrual Pain	1984	ONGOING
	Migraines-Due To Caffeine Withdrawal	2001	ONGOING
	Nasal/Sinus Congestion-Occasional Allergies	1993	ONGOING
	Polycystic Ovarian Syndrome	2003	ONGOING
	Pumpkin Allergy	1978	ONGOING
	Seasonal Allergies	1984	ONGOING
R3026	Anxiety	1994	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R3026	Bipolar Disorder	2004	ONGOING
	Damaged Right Eardrum	2004	ONGOING
	Depression-Mild	1994	ONGOING
	Heartburn-Occasional	2007	ONGOING
	Insomnia	1980	ONGOING
	Post Traumatic Stress Syndrome	2003	ONGOING
	Recurrent Back Pain	1996	ONGOING
R3027	Acne	1993	ONGOING
	Chronic Cough	2005	ONGOING
	Chronic Vaginal Infections	2002	ONGOING
	Dizziness/Lightheadedness Intermittent (Weekly)	1995	ONGOING
	Eczema	1998	ONGOING
	Heartburn	1994	ONGOING
	Hemorrhoids	1995	ONGOING
	Irritable Bowel Syndrome	2001	ONGOING
Mild Asthma	1999	ONGOING	
R3029	Glaucoma Right Eye (Early Stages)	2006	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R3029	Hemorrhoids	2004	ONGOING
	Hives-Due To Penicillin Allergy Episodic	1972	ONGOING
	Incontinence/Bladder Control Problems Minor	2006	ONGOING
	Mold Allergy	2009-03	ONGOING
	Nasal/Sinus Congestion-Due To Allergies	1978	ONGOING
	Penicillin Allergy	1972	ONGOING
	Seasonal Allergies	1978	ONGOING
	Sinus Infections-Occasional	1965	ONGOING
R3030	Heartburn	2005	ONGOING
	Recurrent Back Pain Due To Scoliosis	1981	ONGOING
	Recurrent Rashes Mid Chest	2009-04	ONGOING
	Scoliosis	1981	ONGOING
R3032	Hysterectomy	(b) (6)	(b) (6)
	Natural Post-Menopause	1983-06-01	ONGOING
	Recurrent Back Pain	1977	ONGOING
	Seasonal Allergies	1972	ONGOING
	Sinus Infections	2005	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R4001	Hypercholesterolemia	2007	ONGOING
R4002	Post-Menopausal	1994	ONGOING
R4003	Barrett's Esophagus Hypertension	2005 1987	ONGOING ONGOING
R4006	Occasional Headaches Occasional Nasal Congestion	1999 1999	ONGOING ONGOING
R4008	Recurrent Joint Pain	1979	ONGOING
R4010	Hypertension Postmenopausal Hormone Replacement Therapy	2000 2000	ONGOING ONGOING
R4011	Post Menopausal Hormone Replacement Therapy	1991	ONGOING
R4012	Post Menopausal	1995	ONGOING
R4013	Tension Headache - Occasional	1979	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R4015	Headaches - Occasional	1998	ONGOING
	Nasal Congestion- Periodically	1998	ONGOING
	Post Menopausal Hormone Replacement Therapy	UNK	ONGOING
R4017	Tension Headaches From Work	2008	ONGOING
R4018	Headache - Occasional	2009-03	ONGOING
R4020	Allergic Rhinitis	1989	ONGOING
R4021	Chronic Sinus Congestion	1983	ONGOING
	Depression	1993	ONGOING
R4022	Toenail Fungus	2008-05	2009-10-01
R4023	Post Menopausal	2008-08	ONGOING
R4024	Heartburn	1996	ONGOING
	Insomnia	2006	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R4025	Diabetes Mellitus	2006-04	ONGOING
	Headcold	2004	ONGOING
	Hypertension	2006-04	ONGOING
R4027	Headaches	1987	ONGOING
R4028	Allergic Rhinitis	1961	ONGOING
	Gastroesophageal Reflux	1978	ONGOING
	Hot Flashes	2002	ONGOING
	Restless Leg Syndrome	2004	ONGOING
R4029	Atopic Dermatitis	2000	ONGOING
R4031	Dentures	UNK	ONGOING
R4033	Allergic Rhinitis	1967	ONGOING
	Chronic Constipation	2007	ONGOING
	Migraine Headaches	1981	ONGOING
	Tension Headaches	2004	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R4034	Generalized Myalgia - Chronic	2007	ONGOING
R4035	Seasonal Allergies	1975	ONGOING
R4037	Gastroesophageal Reflux Disease	2003	ONGOING
	Hypertension	2003	ONGOING
	Insomnia	1965	ONGOING
R4038	Diabetes	1986	ONGOING
	Hyperlipidemia	1986	2008
	Hypertension	1986	2008
	Sinus Infection	2007	2008
	Stomach Gas	2004	ONGOING
R4039	Backache	2009	ONGOING
R4040	Heartburn	1997	ONGOING
	Myalgia	1994	ONGOING
	Sinus Headaches	1999	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R4041	Postmenopausal	1992-01-01	ONGOING
R4042	Dentures	1985	ONGOING
R4043	Neck Muscle Strain	2009-05-05	ONGOING
R4045	Hot Flashes	2008-08	ONGOING
R4046	Arthralgia Knee	2004	ONGOING
	Erectile Dysfunction	2004	ONGOING
	Hypercholesterolemia	UNK	ONGOING
	Insomnia	2004-10	ONGOING
	Prostate Cancer	2004	2005-02-17
R4047	Nevus	1962-02-25	2009-05-23
	Tinea Pedis	2006	2009
R4048	Hypercholesterolemia	2009	ONGOING
R4049	Chronic Constipation	2006	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R4049	Chronic Migraine Headaches	2003	ONGOING
	Chronic Nausea	UNK	ONGOING
	Chronic Neck Pain	2002	ONGOING
	Dentures	UNK	ONGOING
	Heartburn	2004	ONGOING
	Overactive Bladder	2007	ONGOING
R4050	Allergic Rhinitis	1999	ONGOING
	Dentures	2000	ONGOING
	Pedal Edema	2009-06-02	ONGOING
R4051	Hypercholesterolemia	1980	ONGOING
R4052	Hypothyroidism	1994	ONGOING
R4054	Hypercholesterolemia	2004	ONGOING
	Hypertension	2004	ONGOING
R4056	Occasional Muscle Aches	2008-12	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R4056	Overweight	UNK	ONGOING
R4058	Back Pain Occasional Headaches	1980 1985	ONGOING ONGOING
R4059	Diabetes Type Ii Hypercholesterolemia Hypertension	2000 1998 2008	ONGOING ONGOING ONGOING
R4060	Gastroesophageal Reflux Disease Hypertension Odontalgia	2001 2003 UNK	ONGOING ONGOING ONGOING
R4063	Hypercholesterolemia Hypertension	2009 2007	ONGOING ONGOING
R4064	Insomnia	2007	ONGOING
R4066	Arthritis Hip	2008-11	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R4067	Acid Reflux	1998	ONGOING
	Fibromyalgia	2007	ONGOING
	Insomnia	1999	ONGOING
	Migraine Headaches	1976	ONGOING
	Occasional Sunburn Skin	1997	ONGOING
R4068	Dentures	1970	ONGOING
	Postmenopausal	1993	ONGOING
R4070	Dyspepsia	2008	ONGOING
R4071	Dyspepsia	2009-06-26	2009-10
R4072	Benign Prostate Hypertrophy	2008	ONGOING
	Erectile Dysfunction	1997	ONGOING
	Genital Herpes	1999	ONGOING
	Neuropathy	2009-03-20	ONGOING
	Occasional Heartburn	2009	ONGOING
R4073	Bipolar Disorder	2006	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R4073	Depression	1985	ONGOING
	Herpes Infection Of Right Eye	2009	ONGOING
	Insomnia	2007	ONGOING
R4075	Arthralgia Knees	2007	ONGOING
R4077	Allergic Rhinitis	2003-06	ONGOING
	Dysmenorrhea	1996	ONGOING
R4078	Heartburn	1985	ONGOING
R4079	Anxiety	1999	ONGOING
	Dermatitis-Hands	2008-10	ONGOING
	Insomnia	2009-05	ONGOING
	Seasonal Allergies	UNK	ONGOING
	Tooth Infection	2009-06-01	2009-06-05
R4081	Post Menopausal	1987	ONGOING
R4082	Back Pain	2005	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R4082	Insomnia	1996	2009-06-10
R4083	Hypertension	2008	ONGOING
R4084	Plantar Fasciitis	2007	ONGOING
R4085	Contact Dermatitis	1982	ONGOING
R4086	Post Menopausal	2000-01	ONGOING
R4087	Hypertension	2005	ONGOING
	Hypothyroidism	1994	ONGOING
	Insomnia	1990	ONGOING
	Occasional Generalized Pain	2000	ONGOING
	Post Menopausal	1990	ONGOING
R4088	Arthralgia	2009-06-15	2009-06-15
	Knee Pain	2009-06-18	2009-06-18
	Seasonal Allergies	2003	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R4088	Sinus Headaches	2005	ONGOING
R4089	Gastroesophageal Reflux Disease	2003	ONGOING
R4090	Dysmenorrhea	1978	ONGOING
R4092	Arthralgia Knee Pain Occasional Insomnia	2009-04-01 1990	ONGOING ONGOING
R4093	Erectile Dysfunction	1999	ONGOING
R4094	Chronic Edema Bilateral Hands And Feet Chronic Leg Cramps Hysterectomy Rheumatoid Arthritis Seasonal Allergies	2008-06 1999 1999 1992 2008	ONGOING ONGOING 1999 ONGOING ONGOING
R4096	Contact Dermatitis	2009-06-23	2010-01-08
R4098	Allergic Rhinitis	2008	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R4098	Gastroesophageal Reflux Disease Sterilization Procedure	2009-03 (b) (6)	ONGOING (b) (6)
R4099	Anxiety Occasional Heartburn Sinusitis	2006 2007 2009-06-16	ONGOING ONGOING 2009-06-19
R4102	Hypertension	2008-11	ONGOING
R4106	Hypertension	2008	ONGOING
R4107	Dysmenorrhea Hypothyroidism Insomnia	UNK 1997 UNK	ONGOING ONGOING ONGOING
R4108	Hypertension	2001	ONGOING
R4109	Headache	UNK	ONGOING
R4110	Headaches	2009-07-23	2009-08-01

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R4112	Back Pain	2007	ONGOING
	Sinusitis	2009-07	2009-07
	Tension Headaches	1998	ONGOING
R4113	Recurrent Rashes	2008-07	ONGOING
R4114	Glaucoma	1997	ONGOING
	Heartburn	2004	ONGOING
	Hypercholesterolemia	1999	ONGOING
	Hypertension	2003	ONGOING
	Osteoporosis Postmenopausal	2009 1999	ONGOING ONGOING
R4115	Past Substance Abuse	1983	2004
R4117	Anxiety	UNK	ONGOING
R4118	Hypercholesterolemia	2008	ONGOING
	Hypertension	2009-01	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R4118	Nasal Congestion Occasional Tension Headache	2009-07-14 2003	2009-07-19 ONGOING
R4119	Foot Pain	2008	ONGOING
R4120	Hypothyroidism Menopausal Symptoms Occasional Sinus Headache Osteopenia	2001 1999 UNK 2007	ONGOING ONGOING ONGOING ONGOING
R4121	Headache	2009-07-15	2009-07-19
R5001	Allergic To Poison Ivy Heartburn - Tomato Induced Intermittent Lightheadedness Secondary To Venipuncture	1967 1995 2009-06-16	ONGOING ONGOING ONGOING
R5002	Anxiety Endometriosis Full Hysterectomy	2008-02 2008-01 (b) (6)	2009-02 2008-02 (b) (6)

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R5003	Insomnia	2008	ONGOING
	Seasonal Allergies	1979	ONGOING
	Shoulder Pain Due To Exercise	2009-06-01	2009-06-01
R5004	Occasional Headaches	1993	ONGOING
	Seasonal Allergies	1985	ONGOING
R5005	High Blood Pressure	2004	ONGOING
	Occasional Constipation	2004	ONGOING
	Occasional Headaches	2004	ONGOING
	Urinary - Incontinence	2000	ONGOING
R5006	Chest Congestion (Cold)	2009-05-15	2009-06-22
	Hot Flashes	2008	ONGOING
	Multiple Cat Bites	2009-06-17	2009-06-24
	Occasional Anxiety Attacks	2003	ONGOING
	Osteoarthritis - Neck	2003	ONGOING
	Seasonal Allergies/Allergic Rhinitis	1985	ONGOING
	Sprained Left Shoulder	2009-06-17	2009-06-24

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R5006	Sprained Right Knee	2009-06-17	2009-06-24
R5008	Anxiety Due To Job Heartburn	1998 2008	ONGOING ONGOING
R5010	Chronic Leg Cramps Due To Occupation Chronic Numbness/Tingling To Legs Due To Occupation Heartburn Nasal Congestion Due To Seasonal Allergies Recurrent Back Pain Due To Occupation Seasonal Allergies Shortness Of Breath Upon Exertion	1999 2003 1996 1980 1975 1980 1999	ONGOING ONGOING ONGOING ONGOING ONGOING ONGOING
R5011	Deaf Right Ear Post Menopausal Tubal Ligation	1964 2008 (b) (6)	ONGOING ONGOING (b) (6)
R5012	Allergic To Snake Serum Chronic Constipation	1979 1960	ONGOING ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R5012	Light Shingles On Abdomen	2008-01	ONGOING
	Occasional Hotflashes	2008-12	ONGOING
	Post Menopausal	2008-10	ONGOING
R5013	Hysterectomy	2008-01	2008-01
	Migraine Headaches	2000	ONGOING
	Nasal/Sinus Congestion	2000	ONGOING
R5014	Recurrent Back Pain From Auto Accident	2004	ONGOING
R5015	Post Menopausal	1997	ONGOING
R5016	Asthma	1999	ONGOING
	High Blood Pressure	1993	ONGOING
	Hot Flashes	1997	ONGOING
	Post Menopausal	2002	ONGOING
R5017	Allergic To Poison Ivy	2009-07-05	ONGOING
	Chronic Flatulence	2008	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R5017	Hot Flashes	2003	ONGOING
	Irregular Heart Beat	1970	ONGOING
	Occasional Headaches	1980	ONGOING
	Total Hysterectomy	2003	2003
R5018	Vasectomy	1994	1994
R5020	Chronic Constipation	1969	ONGOING
	Hemorrhoids	1969	ONGOING
	Intermittent Back Spasms	2008-04-01	ONGOING
	Osteoarthritis	2007	ONGOING
	Ovarian Cyst (Right Ovary)	1995	ONGOING
	Post Menopausal	1996	ONGOING
	Recurrent Joint Pain	2007	ONGOING
R5021	Menstrual Cramps	2009-07-07	2009-07-08
R5022	Acne - Face And Back	2007	ONGOING
	Allergic Rhinitis	1989	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R5022	Allergic To Tylenol	1986	ONGOING
	Asthma	1986	ONGOING
	Gastroesophageal Reflux Disease	2006	ONGOING
	Irritable Bowel Syndrome	2006	ONGOING
	Partial Hysterectomy	2007	2007
	Tubal Ligation	1992	1992
R5023	Acne	2007	ONGOING
	Adult Attention Deficit Disorder	2005	ONGOING
	Degenerative Disc C3-C5	2001	ONGOING
	Pain From Degenerative Disc C3-C5	2001	ONGOING
	Tubal Ligation	1999	1999
R5024	Hot Flashes	2003	ONGOING
	Insomnia	2009-02	ONGOING
	Post Menopausal	2003	ONGOING
	Shortness Of Breath Upon Exertion (Sports)	1990	ONGOING
	Total Hysterectomy	(b) (6)	(b) (6) (b)
R5025	Blocked Sinuses	2004	ONGOING

NOTE: UNK=UNKNOWN.

Listing 16.2.4-3 Medical History by Subject

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Study Population: ITT

Subject Number	Diagnosis/Procedure	Date of Onset	Date of Resolution
R5025	Chronic Obstructive Pulmonary Disease	2009-05	ONGOING
	Flatulence Due To Ingestion Of Milk	2009-04	ONGOING
	Hypothyroidism	2004	ONGOING
	Shortness Of Breath Upon Exertion	2008	ONGOING
	Temporomandibular Joint Disorder	1982	ONGOING
R5026	Acne, Back, Chest, Facial	1980	ONGOING
	Recurrent Joint Pain - Right Knee	2004	ONGOING
	Shortness Of Breath Upon Exertion	1990	ONGOING
R5027	Iud Insertion	2008	(b) (6)
R5028	Acne	UNK	ONGOING
	Hemorrhoids	1976	ONGOING
	Post Menopausal	2007-02	ONGOING
	Tubal Ligation	(b) (6)	(b) (6)

NOTE: UNK=UNKNOWN.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1001	Yes	2009-02-18	Age subject began smoking daily	26	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 2	Acupuncture x1 & hypnosis x1
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	Twice, the subject tried to quit by not smoking.
R1002	Yes	2009-02-18	Age subject began smoking daily	18	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1002	Yes	2009-02-18	Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	No smoking cessation aides were used
R1003	Yes	2009-02-18	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1003	Yes	2009-02-18	Has subject used smokeless tobacco in the past?	No	Patches Wellbutrin used once in 2005 & chantix used once in 2008 Quit smart program x2 & hypnosis
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 3	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R1004	Yes	2009-03-02	Age subject began smoking daily	19	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1004	Yes	2009-03-02	Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 7	Subject used the patch once and has used nicotine gum about 6 times.
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R1005	Yes	2009-03-02	Age subject began smoking daily	16	Patches, gum, nicotine inhaler & 2 tries of the filter 4 step stop smoking method.
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 5	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1005	Yes	2009-03-02	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix Subject tried each once: hypnosis, fake cigarettes and the life styles calculator method. Subject has had several new years resolutions where she just stopped smoking.
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 3	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 6	
R1006	Yes	2009-03-03	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1006	Yes	2009-03-03	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R1007	Yes	2009-03-05	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1007	Yes	2009-03-05	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 3	Cold turkey
R1008	Yes	2009-03-02	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 11	Nicorette gum 5x & patches 6x
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Hypnosis
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1009	Yes	2009-03-02	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Has used patch, gum
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 4	Cold laser, hypnosis x2, smokenders
R1010	Yes	2009-03-19	Age subject began smoking daily	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1010	Yes	2009-03-19	Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Patches x2
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R1011	Yes	2009-04-03	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1011	Yes	2009-04-03	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	Cold turkey
R1012	Yes	2009-04-01	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1012	Yes	2009-04-01	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	Cold turkey
R1013	Yes	2009-04-08	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1013	Yes	2009-04-08	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin- successfully quit for 7 years
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R1014	Yes	2009-04-08	Age subject began smoking daily	27	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1014	Yes	2009-04-08	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R1015	Yes	2009-04-16	Age subject began smoking daily	13	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1015	Yes	2009-04-16	Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R1016	Yes	2009-05-08	Age subject began smoking daily	14	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1017	Yes	2009-05-08	Age subject began smoking daily	19	
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R1018	Yes	2009-05-06	Age subject began smoking daily	13	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1018	Yes	2009-05-06	Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 06	3x-patch,2x-gum,1x-inhaler
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 02	Wellbutrin,chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 02	Hypnosis
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R1019	Yes	2009-05-08	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1019	Yes	2009-05-08	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey(quit for 3 months)
R1020	Yes	2009-05-29	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	28	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1020	Yes	2009-05-29	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 10	Cold turkey
R1021	Yes	2009-05-29	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patches

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1021	Yes	2009-05-29	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R1022	Yes	2009-05-29	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1022	Yes	2009-05-29	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R1023	Yes	2009-06-11	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 4	1 time w/ gum; 3 times w/ patches
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, Unk	Hypnosis

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1023	Yes	2009-06-11	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 7	Cold turkey
R1024	Yes	2009-06-16	Age subject began smoking daily	20	
			Average number of cigarettes smoked per day over the past year	25	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1025	Yes	2009-06-16	Age subject began smoking daily	12	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 6	Patch(3x),inhaler(1x),gum(2x).
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 3	Chantix(2x), wellbutrin(1x)
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 2	Laser(1x), hypnosis(1x)
R1026	Yes	2009-06-16	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 4	Cold turkey
			Age subject began smoking daily	16	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1026	Yes	2009-06-16	Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R1027	Yes	2009-06-25	Age subject began smoking daily	19	
			Average number of cigarettes smoked per day over the past year	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1027	Yes	2009-06-25	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	Cold turkey
R1028	Yes	2009-06-25	Age subject began smoking daily	24	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1028	Yes	2009-06-25	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R1029	Yes	2009-06-25	Age subject began smoking daily	14	
			Average number of cigarettes smoked per day over the past year	25	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Nicoderm

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1029	Yes	2009-06-25	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R1030	Yes	2009-07-07	Age subject began smoking daily	20	Nicotine patch(1),lozenges(2) Wellbutrin(1), chantix(1)
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 3	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1030	Yes	2009-07-07	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Hypnosis
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R1031	Yes	2009-07-09	Age subject began smoking daily	14	Nicorette gum
			Average number of cigarettes smoked per day over the past year	12	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	Hypnosis
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1031	Yes	2009-07-09	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	Cold turkey
R1032	Yes	2009-07-09	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	On her own without the use of any smoking cessation aids

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1033	Yes	2009-07-07	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Subject had used wellbutrin in 2004
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Subject used cigarrest in 2007
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R1034	Yes	2009-07-23	Age subject began smoking daily	17	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1034	Yes	2009-07-23	Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R1035	Yes	2009-07-28	Age subject began smoking daily	20	
			Average number of cigarettes smoked per day over the past year	30	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1035	Yes	2009-07-28	Has subject used smokeless tobacco in the past?	No	Patches
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R1036	Yes	2009-07-28	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	40	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1036	Yes	2009-07-28	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	Chantix
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R1037	Yes	2009-07-28	Age subject began smoking daily	17	3 times nicorette gum
			Average number of cigarettes smoked per day over the past year	40	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 3	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R1037	Yes	2009-07-28	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R2001	Yes	2009-03-05	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2001	Yes	2009-03-05	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	Subject states cold turkey in 2005
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, Once	
R2002	Yes	2009-03-06	Age subject began smoking daily	18	Walgreens generic brand nicotine patch
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2002	Yes	2009-03-06	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey but not successful
R2003	Yes	2009-03-05	Age subject began smoking daily	17	Subject used nicotine patches and gum for approximately 2 weeks. Wellbutrin reported and used since 2003 with last use occurring 7 months ago approximately september of 2008.
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, Occasion	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, Multiple	Multiple attempts using cold turkey method throughout the years.

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2004	Yes	2009-03-11	Age subject began smoking daily	20	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, Multiple	Tried multiple times during the years of 2002 and 2005 by cold turkey method.
R2005	Yes	2009-03-12	Age subject began smoking daily	17	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2005	Yes	2009-03-12	Average number of cigarettes smoked per day over the past year	11	
			Has subject used smokeless tobacco in the past?	Yes	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Reports using zyban once daily beginning january of 2000 and ending july of 2000 for smoking cessation purposes.
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	Tried cold turkey in january 1984 and july 2000.
R2006	Yes	2009-03-12	Age subject began smoking daily	14	
			Average number of cigarettes smoked per day over the past year	25	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2006	Yes	2009-03-12	Has subject used smokeless tobacco in the past?	No	Nicotine patches
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, Multiple	
R2007	Yes	2009-04-07	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Subject stated cold turkey once but wasn't successful.
			Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2007	Yes	2009-04-07	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Zyban (wellbutrin)
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, Numerous	Cold turkey
R2008	Yes	2009-04-07	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2008	Yes	2009-04-07	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R2009	Yes	2009-04-08	Age subject began smoking daily	14	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicotine patches once 2006
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin once 2006

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2009	Yes	2009-04-08	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Acupuncture once 2007
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 3	Subject attempted cold turkey three times and was unsuccessful
R2010	Yes	2009-04-09	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Chantix once 2008 and wellbutrin once 2007
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2010	Yes	2009-04-09	Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R2011	Yes	2009-04-10	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Nicorette gum 1988, patches 1990
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix 2007
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey 1980

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2012	Yes	2009-04-15	Age subject began smoking daily	13	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 3	Nicotine patches 2007 & 2008, nicotine gum 2006
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin 2003
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 3	Hypnotism 2003, 2004, 2008
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey 2003
R2013	Yes	2009-04-15	Age subject began smoking daily	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2013	Yes	2009-04-15	Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Nicorette gum 2007, nicotine patches 2007
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin 2005
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 3	Cold turkey 2004, 2006, 2008
R2014	Yes	2009-04-24	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2014	Yes	2009-04-24	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Zyban 1998
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	Cold turkey 1998, 1999
R2015	Yes	2009-04-23	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2015	Yes	2009-04-23	Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Patches 2001, gum 2003
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin 2002
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 4	Cold turkey 1998, 2001, 2003, 2007
R2016	Yes	2009-04-24	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 3	Lozenge 2006, 2007, 2008

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2016	Yes	2009-04-24	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey through 1994 -2000
R2017	Yes	2009-04-27	Age subject began smoking daily	12	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicorette gum 2004
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin 2007

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2017	Yes	2009-04-27	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	Cold turkey 1990 through 1996 quit smoking due to a pregnancy.
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	
R2018	Yes	2009-05-07	Age subject began smoking daily	25	Nicotine patches 2006-2007
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2018	Yes	2009-05-07	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey 2007
R2019	Yes	2009-05-12	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Patches 2001, gum 2000
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Wellbutrin 2004, chantix 2007
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 6	Cold turkey 1999, 2000, 2002, 2003, 2006, 2007

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2020	Yes	2009-05-14	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicorette gum 1998
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin 1999
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 4	Cold turkey 1996, 1998, 2001, 2009
R2021	Yes	2009-05-27	Age subject began smoking daily	17	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2021	Yes	2009-05-27	Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey 2008
R2022	Yes	2009-06-18	Age subject began smoking daily	43	
			Average number of cigarettes smoked per day over the past year	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2022	Yes	2009-06-18	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R2023	Yes	2009-06-18	Age subject began smoking daily	25	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2023	Yes	2009-06-18	Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patches 2006
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	
R2024	Yes	2009-06-26	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2024	Yes	2009-06-26	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix 2008
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 4	
R2025	Yes	2009-06-29	Age subject began smoking daily	19	Patches 2008
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2025	Yes	2009-06-29	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey 2005
R2026	Yes	2009-06-30	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	25	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Nicotine patches 2007, gum 2007
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Wellbutrin 1998, chantix 2007
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 2	Hypnotism 1984, acupuncture 1979

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2026	Yes	2009-06-30	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 5	Cold turkey 1976, 1978, 1982, 1990, 1991
R2027	Yes	2009-07-01	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patches 1997
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin 2002
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Hypnotism 1994
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey 1980

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2028	Yes	2009-07-08	Age subject began smoking daily	14	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Lozenges 2006
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin 1999
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
R2029	Yes	2009-07-09	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 3	Cold turkey
			Age subject began smoking daily	15	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2029	Yes	2009-07-09	Average number of cigarettes smoked per day over the past year	50	
			Has subject used smokeless tobacco in the past?	Yes	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey 1998
R2030	Yes	2009-07-16	Age subject began smoking daily	14	
			Average number of cigarettes smoked per day over the past year	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2030	Yes	2009-07-16	Has subject used smokeless tobacco in the past?	No	Commit tablets 2003
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	
R2031	Yes	2009-07-20	Age subject began smoking daily	13	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2031	Yes	2009-07-20	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R2032	Yes	2009-07-20	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R2032	Yes	2009-07-20	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey 2000
R3001	Yes	2009-04-29	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3001	Yes	2009-04-29	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 30	No aide
R3002	Yes	2009-02-23	Age subject began smoking daily	31	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicoderm 2005
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin 2004
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3002	Yes	2009-02-23	Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R3003	Yes	2009-02-23	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patch 1996
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 3	Chantix 2006, 2007, 2008
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Hypnosis 1980
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 4	No aide 2005, 1991, 1992, 1993

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3004	Yes	2009-02-18	Age subject began smoking daily	13	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicorette gum in 2006
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
R3005	Yes	2009-02-25	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	2 attemps no aide in 2008
			Age subject began smoking daily	18	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3005	Yes	2009-02-25	Average number of cigarettes smoked per day over the past year	18	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 4	Gum 1982, 1987, 1993 patch 1998
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Without aide in 1992
R3006	Yes	2009-02-25	Age subject began smoking daily	19	
			Average number of cigarettes smoked per day over the past year	10	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3006	Yes	2009-02-25	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R3007	Yes	2009-02-25	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	Yes	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3007	Yes	2009-02-25	Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 5	Nicorette gum
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 5	
R3008	Yes	2009-04-28	Age subject began smoking daily	16	Lozenge once. patch once.
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	Yes	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3008	Yes	2009-04-28	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	No aid
R3009	Yes	2009-02-25	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	18	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 3	Gum 2 times and patch 1 time
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3009	Yes	2009-02-25	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 4	Acupuncture 3 times hypnosis 1 time
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 3	No aide
R3010	Yes	2009-03-05	Age subject began smoking daily	13	
			Average number of cigarettes smoked per day over the past year	12	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patch 2 years ago for "a couple days"
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3010	Yes	2009-03-05	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	1993 and 2000 no aide
R3011	Yes	2009-03-12	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 5	No aide

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3012	Yes	2009-04-22	Age subject began smoking daily	13	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 3	2 times nicorette, 1 time patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Zyban
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
R3013	Yes	2009-04-28	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 6	Without aide
			Age subject began smoking daily	22	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3013	Yes	2009-04-28	Average number of cigarettes smoked per day over the past year	18	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Once without aid
R3014	Yes	2009-03-26	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3014	Yes	2009-03-26	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R3015	Yes	2009-04-28	Age subject began smoking daily	21	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3015	Yes	2009-04-28	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 10	No aide
R3016	Yes	2009-03-31	Age subject began smoking daily	25	
			Average number of cigarettes smoked per day over the past year	25	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3016	Yes	2009-03-31	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	No aide
R3017	Yes	2009-04-08	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	Yes	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicorette
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3017	Yes	2009-04-08	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	No aide
R3018	Yes	2009-04-08	Age subject began smoking daily	25	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3018	Yes	2009-04-08	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	In 1995 and 2002 no aide
R3019	Yes	2009-04-16	Age subject began smoking daily	13	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 4	Attepted to quit using nicotine patch 4 times
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin once
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Attempted hypnosis once
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 4	Four attempts with no aide

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3020	Yes	2009-04-23	Age subject began smoking daily	21	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Gum 2006 and patch 2005
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
R3021	Yes	2009-04-23	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 6	No aide
			Age subject began smoking daily	9	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3021	Yes	2009-04-23	Average number of cigarettes smoked per day over the past year	45	
			Has subject used smokeless tobacco in the past?	Yes	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 5	Nicotine patch, five times
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 6	No aide, six times
R3022	Yes	2009-04-30	Age subject began smoking daily	13	
			Average number of cigarettes smoked per day over the past year	40	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3022	Yes	2009-04-30	Has subject used smokeless tobacco in the past?	No	Patch in 1995, 1997 and 1998 gum in 2007 and 2008 Wellbutrin 1999 and chantix 2007
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 5	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 5	
R3023	Yes	2009-04-30	Age subject began smoking daily	29	No aide 2004, 1992, 1998, 1999 and 2001
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3023	Yes	2009-04-30	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 4	No aide
R3024	Yes	2009-04-29	Age subject began smoking daily	21	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3024	Yes	2009-04-29	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R3025	Yes	2009-05-06	Age subject began smoking daily	13	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	Yes	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicotine patch, once
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3025	Yes	2009-05-06	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	No aide, once
R3026	Yes	2009-05-07	Age subject began smoking daily	21	
			Average number of cigarettes smoked per day over the past year	12	
			Has subject used smokeless tobacco in the past?	Yes	Wintergreen husky long cut 2-3 times per week
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 5	Patch in 2003 and 2005 gum in 2003, 2005 and 2006
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Chantix 2006 wellbutrin 2006
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3026	Yes	2009-05-07	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	No aide 1997
R3027	Yes	2009-05-06	Age subject began smoking daily	12	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	Yes	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicotine patch, once
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin, once
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 4	No aide, four times

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3028	Yes	2009-05-07	Age subject began smoking daily	10	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R3029	Yes	2009-05-06	Age subject began smoking daily	13	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3029	Yes	2009-05-06	Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	Yes	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicotine patch, once
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix, once
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Without aide, once
R3030	Yes	2009-05-07	Age subject began smoking daily	10	
			Average number of cigarettes smoked per day over the past year	12	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3030	Yes	2009-05-07	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	No aide, once
R3031	Yes	2009-05-06	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	Yes	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3031	Yes	2009-05-06	Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicotine patch for 3 weeks
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R3032	Yes	2009-05-07	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R3032	Yes	2009-05-07	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	No aide
R4001	Yes	2009-02-20	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Chantix, a pill but cannot remember name

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4001	Yes	2009-02-20	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 5	Cold turkey
R4002	Yes	2009-02-20	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 2	Smoking cessation class

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4002	Yes	2009-02-20	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	Cold turkey
R4003	Yes	2009-02-20	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Nicoderm
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Zyban, chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4004	Yes	2009-02-25	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 3	Unknown
R4005	Yes	2009-02-25	Age subject began smoking daily	17	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4005	Yes	2009-02-25	Average number of cigarettes smoked per day over the past year	21	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	Cold turkey
R4006	Yes	2009-03-08	Age subject began smoking daily	14	
			Average number of cigarettes smoked per day over the past year	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4006	Yes	2009-03-08	Has subject used smokeless tobacco in the past?	No	Patches
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4007	Yes	2009-03-03	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4007	Yes	2009-03-03	Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 3	Nicotine lozenges, nicorette gum x2
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 12	Cold turkey
R4008	Yes	2009-02-26	Age subject began smoking daily	8	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Nicorette gum

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4008	Yes	2009-02-26	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin Hypnosis, mineral/vitamin combination, lavender substance behind ears, acupuncture
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 6	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4009	Yes	2009-02-26	Age subject began smoking daily	20	Chantix
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4009	Yes	2009-02-26	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4010	Yes	2009-02-26	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4010	Yes	2009-02-26	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4011	Yes	2009-03-04	Age subject began smoking daily	20	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicorette
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4012	Yes	2009-03-04	Age subject began smoking daily	21	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patches
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Hypnosis
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 4	Cold turkey (x4)
R4013	Yes	2009-03-04	Age subject began smoking daily	16	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4013	Yes	2009-03-04	Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 4	Cold turkey
R4014	Yes	2009-03-04	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment	
R4014	Yes	2009-03-04	Has subject used smokeless tobacco in the past?	No	Nicoderm, nicorette	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2		
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1		Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No		
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 6		Cold turkey
R4015	Yes	2009-03-04	Age subject began smoking daily	19		
			Average number of cigarettes smoked per day over the past year	20		
			Has subject used smokeless tobacco in the past?	No		

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4015	Yes	2009-03-04	Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Gum
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4016	Yes	2009-03-12	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patch

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4016	Yes	2009-03-12	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	Cold turkey
R4017	Yes	2009-03-08	Age subject began smoking daily	21	
			Average number of cigarettes smoked per day over the past year	21	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patches
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4017	Yes	2009-03-08	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	On own
R4018	Yes	2009-03-10	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4018	Yes	2009-03-10	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	On own
R4019	Yes	2009-03-20	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	13	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicorette
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 7	Cold turkey

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4020	Yes	2009-03-20	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patches
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Smoke away program
R4021	Yes	2009-03-20	Age subject began smoking daily	18	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4021	Yes	2009-03-20	Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 6	Methods unknown
R4022	Yes	2009-03-26	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	12	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4022	Yes	2009-03-26	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Unknown
R4023	Yes	2009-03-26	Age subject began smoking daily	25	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4023	Yes	2009-03-26	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 3	
R4024	Yes	2009-03-26	Age subject began smoking daily	11	
			Average number of cigarettes smoked per day over the past year	13	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4024	Yes	2009-03-26	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 12	Unknown
R4025	Yes	2009-03-20	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	40	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 4	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 3	Chantix x 1, wellbutrin x 2
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4025	Yes	2009-03-20	Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4026	Yes	2009-04-09	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4027	Yes	2009-04-13	Age subject began smoking daily	22	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 3	Tried to quit cold turkey in 2001, 2002, 2008
R4028	Yes	2009-04-16	Age subject began smoking daily	18	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4028	Yes	2009-04-16	Average number of cigarettes smoked per day over the past year	40	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Support group
R4029	Yes	2009-04-16	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	18	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4029	Yes	2009-04-16	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 4	Gum
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 14	Cold turkey
R4030	Yes	2009-04-15	Age subject began smoking daily	42	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4030	Yes	2009-04-15	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4031	Yes	2009-04-20	Age subject began smoking daily	13	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 5	Patch

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4031	Yes	2009-04-20	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 3	Wellbutrin, chantix, zyban
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4032	Yes	2009-04-15	Age subject began smoking daily	15	Patch
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4032	Yes	2009-04-15	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4033	Yes	2009-04-27	Age subject began smoking daily	29	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patch-2004
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4033	Yes	2009-04-27	Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4034	Yes	2009-04-15	Age subject began smoking daily	20	
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4035	Yes	2009-04-29	Age subject began smoking daily	13	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicoderm
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
R4036	Yes	2009-04-27	Age subject began smoking daily	13	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4036	Yes	2009-04-27	Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4037	Yes	2009-04-28	Age subject began smoking daily	12	
			Average number of cigarettes smoked per day over the past year	10	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4037	Yes	2009-04-28	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 4	Cold turkey
R4038	Yes	2009-04-29	Age subject began smoking daily	19	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4038	Yes	2009-04-29	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4039	Yes	2009-04-29	Age subject began smoking daily	12	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4039	Yes	2009-04-29	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4040	Yes	2009-04-29	Age subject began smoking daily	13	
			Average number of cigarettes smoked per day over the past year	40	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4040	Yes	2009-04-29	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	On own
R4041	Yes	2009-04-27	Age subject began smoking daily	46	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4041	Yes	2009-04-27	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 3	Cold turkey
R4042	Yes	2009-04-29	Age subject began smoking daily	13	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4043	Yes	2009-04-29	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Commit
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Smoking class
R4044	Yes	2009-04-29	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
			Age subject began smoking daily	19	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4044	Yes	2009-04-29	Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4045	Yes	2009-04-28	Age subject began smoking daily	14	
			Average number of cigarettes smoked per day over the past year	16	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4045	Yes	2009-04-28	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4046	Yes	2009-04-29	Age subject began smoking daily	20	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment	
R4046	Yes	2009-04-29	Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 5	Patch x 2, nicorette gum x 3	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No		
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1		Hypnosis
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No		
R4047	Yes	2009-04-21	Age subject began smoking daily	16		
			Average number of cigarettes smoked per day over the past year	24		
			Has subject used smokeless tobacco in the past?	No		
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No		

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4047	Yes	2009-04-21	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	Self motivation x 2
R4048	Yes	2009-04-28	Age subject began smoking daily	25	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicotine patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4048	Yes	2009-04-28	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	Cold turkey
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 4	
R4049	Yes	2009-04-29	Age subject began smoking daily	15	Patches
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4049	Yes	2009-04-29	Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4050	Yes	2009-06-02	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4051	Yes	2009-06-02	Age subject began smoking daily	19	
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4052	Yes	2009-06-02	Age subject began smoking daily	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4052	Yes	2009-06-02	Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4053	Yes	2009-06-02	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4053	Yes	2009-06-02	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patches
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Chantix, wellbutrin
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 10	Cold turkey
R4054	Yes	2009-05-26	Age subject began smoking daily	13	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4054	Yes	2009-05-26	Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Patches x 2
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Wellbutrin, chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4055	Yes	2009-05-28	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patches

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4055	Yes	2009-05-28	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Class
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4056	Yes	2009-05-29	Age subject began smoking daily	22	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4056	Yes	2009-05-29	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Hypnotized
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4057	Yes	2009-05-27	Age subject began smoking daily	24	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4057	Yes	2009-05-27	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 5	Cold turkey
R4058	Yes	2009-05-29	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Nicoderm patches x 2
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 3	For pregnancy

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4059	Yes	2009-05-29	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Quit for 13 years-1980
R4060	Yes	2009-05-28	Age subject began smoking daily	16	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4060	Yes	2009-05-28	Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicotine samples
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4061	Yes	2009-06-10	Age subject began smoking daily	11	
			Average number of cigarettes smoked per day over the past year	25	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4061	Yes	2009-06-10	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Wellbutrin, chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Hypnosis
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4062	Yes	2009-06-10	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4062	Yes	2009-06-10	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	Cold turkey
R4063	Yes	2009-06-10	Age subject began smoking daily	20	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicorette gum

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4063	Yes	2009-06-10	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 6	Cold turkey
R4064	Yes	2009-06-08	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4064	Yes	2009-06-08	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4065	Yes	2009-06-10	Age subject began smoking daily	20	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4065	Yes	2009-06-10	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4066	Yes	2009-06-08	Age subject began smoking daily	21	
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicotine patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Artificial cigarette that holds filters
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4067	Yes	2009-06-08	Age subject began smoking daily	14	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 7	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
R4068	Yes	2009-06-08	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 7	Cold turkey
			Age subject began smoking daily	16	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4068	Yes	2009-06-08	Average number of cigarettes smoked per day over the past year	25	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 3	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 3	Cold turkey
R4069	Yes	2009-06-10	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4069	Yes	2009-06-10	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Smokenders
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4070	Yes	2009-06-12	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4070	Yes	2009-06-12	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4071	Yes	2009-06-12	Age subject began smoking daily	21	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicotine gum

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4071	Yes	2009-06-12	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4072	Yes	2009-06-12	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4072	Yes	2009-06-12	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, Unk	Cold turkey
R4073	Yes	2009-06-22	Age subject began smoking daily	20	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Patches, lozenges
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 2	Hypnosis

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4073	Yes	2009-06-22	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 6	Pregnancy/nursing
R4074	Yes	2009-06-22	Age subject began smoking daily	22	
			Average number of cigarettes smoked per day over the past year	12	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 3	Cold

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4075	Yes	2009-06-22	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	25	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Nicorette
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
R4076	Yes	2009-06-22	Age subject began smoking daily	13	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4076	Yes	2009-06-22	Average number of cigarettes smoked per day over the past year	35	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patches
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Wellbutrin, chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4077	Yes	2009-06-22	Age subject began smoking daily	23	
			Average number of cigarettes smoked per day over the past year	23	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4077	Yes	2009-06-22	Has subject used smokeless tobacco in the past?	No	Patch
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, Unk	
R4078	Yes	2009-06-22	Age subject began smoking daily	20	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4078	Yes	2009-06-22	Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicotine nose spray
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 6	
R4079	Yes	2009-06-22	Age subject began smoking daily	14	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4079	Yes	2009-06-22	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4080	Yes	2009-06-22	Age subject began smoking daily	23	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4080	Yes	2009-06-22	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4081	Yes	2009-06-22	Age subject began smoking daily	34	
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicoderm patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Got hypnotized

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4081	Yes	2009-06-22	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4082	Yes	2009-06-22	Age subject began smoking daily	13	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 50	Tried to quit on own

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4083	Yes	2009-06-19	Age subject began smoking daily	20	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Nicotine gum
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4084	Yes	2009-06-12	Age subject began smoking daily	9	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4084	Yes	2009-06-12	Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicotine patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4085	Yes	2009-06-08	Age subject began smoking daily	32	
			Average number of cigarettes smoked per day over the past year	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4085	Yes	2009-06-08	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4086	Yes	2009-06-24	Age subject began smoking daily	21	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4086	Yes	2009-06-24	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	Cold turkey
R4087	Yes	2009-06-24	Age subject began smoking daily	45	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4087	Yes	2009-06-24	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4088	Yes	2009-06-24	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4088	Yes	2009-06-24	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4089	Yes	2009-06-24	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 4	Gum x2 and patch x2
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin 2001
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Hypnotherapy

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4089	Yes	2009-06-24	Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4090	Yes	2009-06-24	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 4	Gum x2, nicotine pop x1, patch x1
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Hypnosis
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4091	Yes	2009-06-22	Age subject began smoking daily	14	
			Average number of cigarettes smoked per day over the past year	18	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 4	When pregnant
R4092	Yes	2009-06-22	Age subject began smoking daily	14	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4092	Yes	2009-06-22	Average number of cigarettes smoked per day over the past year	60	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, Unk	Cold turkey
R4093	Yes	2009-05-26	Age subject began smoking daily	40	
			Average number of cigarettes smoked per day over the past year	15	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4093	Yes	2009-05-26	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4094	Yes	2009-06-26	Age subject began smoking daily	25	
			Average number of cigarettes smoked per day over the past year	12	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4094	Yes	2009-06-26	Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, Many	
R4095	Yes	2009-06-26	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4095	Yes	2009-06-26	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4096	Yes	2009-06-26	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	13	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4096	Yes	2009-06-26	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 5	Cold turkey
R4097	Yes	2009-06-26	Age subject began smoking daily	10	
			Average number of cigarettes smoked per day over the past year	23	
			Has subject used smokeless tobacco in the past?	Yes	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, Unk	Chewing tobacco
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4097	Yes	2009-06-26	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4098	Yes	2009-06-26	Age subject began smoking daily	20	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4099	Yes	2009-06-26	Age subject began smoking daily	17	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4100	Yes	2009-06-26	Age subject began smoking daily	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4100	Yes	2009-06-26	Average number of cigarettes smoked per day over the past year	12	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Hypnotized
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4101	Yes	2009-06-26	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	15	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4101	Yes	2009-06-26	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	Cold turkey
R4102	Yes	2009-06-26	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4102	Yes	2009-06-26	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	On own
R4103	Yes	2009-06-26	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	13	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4103	Yes	2009-06-26	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Zyban
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4104	Yes	2009-07-10	Age subject began smoking daily	14	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4104	Yes	2009-07-10	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4105	Yes	2009-07-20	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4105	Yes	2009-07-20	Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4106	Yes	2009-07-20	Age subject began smoking daily	14	
			Average number of cigarettes smoked per day over the past year	11	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, Unk	On own

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4107	Yes	2009-07-20	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Wellbutrin x1, chantix x1
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
R4108	Yes	2009-07-10	Age subject began smoking daily	24	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4108	Yes	2009-07-10	Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, Unk	Cold turkey
R4109	Yes	2009-07-17	Age subject began smoking daily	19	
			Average number of cigarettes smoked per day over the past year	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4109	Yes	2009-07-17	Has subject used smokeless tobacco in the past?	No	Patches
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 5	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4110	Yes	2009-07-10	Age subject began smoking daily	21	
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4110	Yes	2009-07-10	Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Nicoderm, nicotine lollipop
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Hypnotist
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4111	Yes	2009-07-20	Age subject began smoking daily	25	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4111	Yes	2009-07-20	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4112	Yes	2009-07-17	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4112	Yes	2009-07-17	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	Cold turkey
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 5	
R4113	Yes	2009-07-20	Age subject began smoking daily	15	Nicotine gum, patches and inhalers
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 3	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4113	Yes	2009-07-20	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4114	Yes	2009-07-20	Age subject began smoking daily	49	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Cessation program
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4115	Yes	2009-07-20	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	35	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
R4116	Yes	2009-07-20	Age subject began smoking daily	16	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4116	Yes	2009-07-20	Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 3	Cold turkey
R4117	Yes	2009-07-17	Age subject began smoking daily	19	
			Average number of cigarettes smoked per day over the past year	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4117	Yes	2009-07-17	Has subject used smokeless tobacco in the past?	No	Chantix
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4118	Yes	2009-07-20	Age subject began smoking daily	13	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4118	Yes	2009-07-20	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Cold turkey
R4119	Yes	2009-07-20	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4119	Yes	2009-07-20	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R4120	Yes	2009-07-20	Age subject began smoking daily	21	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4120	Yes	2009-07-20	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 3	On own due to pregnancy
R4121	Yes	2009-07-20	Age subject began smoking daily	14	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R4121	Yes	2009-07-20	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 3	Cold turkey
R5001	Yes	2009-06-16	Age subject began smoking daily	8	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	"cold turkey" for 2 years

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5002	Yes	2009-06-16	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Tried to quit without using or taking anything
R5003	Yes	2009-06-16	Age subject began smoking daily	13	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5003	Yes	2009-06-16	Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R5004	Yes	2009-06-22	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	15	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5004	Yes	2009-06-22	Has subject used smokeless tobacco in the past?	No	Subject tried gum once
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 6	
R5005	Yes	2009-06-23	Age subject began smoking daily	23	
			Average number of cigarettes smoked per day over the past year	12	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5005	Yes	2009-06-23	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	Wellbutrin
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R5006	Yes	2009-06-22	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5006	Yes	2009-06-22	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Wellbutrin
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Smokestoppers
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 5	Cold turkey
R5007	Yes	2009-06-22	Age subject began smoking daily	26	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5007	Yes	2009-06-22	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	Just tried to stop on own
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	
R5008	Yes	2009-06-30	Age subject began smoking daily	21	Subject tried nicorette twice and tried patch once Subject used chantix
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	Yes	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 3	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5008	Yes	2009-06-30	Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R5009	Yes	2009-06-29	Age subject began smoking daily	37	
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5010	Yes	2009-06-29	Age subject began smoking daily	20	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Self discipline with no success
R5011	Yes	2009-06-23	Age subject began smoking daily	16	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5011	Yes	2009-06-23	Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R5012	Yes	2009-07-06	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	60	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5012	Yes	2009-07-06	Has subject used smokeless tobacco in the past?	No	Nicotine gum had very bad dreams and nausea. stopped taking it after 7 days
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
R5013	Yes	2009-07-06	Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
			Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5013	Yes	2009-07-06	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	Without aid
R5014	Yes	2009-07-07	Age subject began smoking daily	19	
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5014	Yes	2009-07-07	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R5015	Yes	2009-07-06	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	30	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Nicorette gum
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Zyban

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5015	Yes	2009-07-06	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R5016	Yes	2009-07-13	Age subject began smoking daily	16	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 4	Target brand "nicotine patch"(3 times); nicotine gum (1 time)
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Wellbutrin
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5016	Yes	2009-07-13	Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R5017	Yes	2009-07-13	Age subject began smoking daily	51	
			Average number of cigarettes smoked per day over the past year	10	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 4	Nicotine gum - twice; nicoderm patch - twice
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Chantix once
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5018	Yes	2009-07-13	Age subject began smoking daily	15	
			Average number of cigarettes smoked per day over the past year	15	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 3	Nicotine patch
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
R5019	Yes	2009-07-14	Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	Cold turkey
			Age subject began smoking daily	15	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5019	Yes	2009-07-14	Average number of cigarettes smoked per day over the past year	25	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 4	Subject tried 4 times to quit on his own without using any cessation aids
R5020	Yes	2009-07-14	Age subject began smoking daily	38	
			Average number of cigarettes smoked per day over the past year	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5020	Yes	2009-07-14	Has subject used smokeless tobacco in the past?	No	Nicorette Attempted twice using wellbutrin
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R5021	Yes	2009-07-13	Age subject began smoking daily	23	
			Average number of cigarettes smoked per day over the past year	12	
			Has subject used smokeless tobacco in the past?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5021	Yes	2009-07-13	Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R5022	Yes	2009-07-20	Age subject began smoking daily	14	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 1	Nicorette

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5022	Yes	2009-07-20	Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 3	Once with wellbutrin but does not recall the name of other two pharmaceuticals used
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R5023	Yes	2009-07-14	Age subject began smoking daily	24	Wellbutrin
			Average number of cigarettes smoked per day over the past year	12	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5023	Yes	2009-07-14	Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	Tried cold turkey
R5024	Yes	2009-07-14	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5024	Yes	2009-07-14	Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R5025	Yes	2009-07-21	Age subject began smoking daily	21	
			Average number of cigarettes smoked per day over the past year	40	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 2	On their own - no aids

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5026	Yes	2009-06-30	Age subject began smoking daily	18	
			Average number of cigarettes smoked per day over the past year	20	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of Nicotine Replacement Therapy (NRT)? If yes, how many times?	No	
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	No	
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	Yes, 1	Quit once cold turkey at age 22 for 3 months
R5027	Yes	2009-07-21	Age subject began smoking daily	21	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5027	Yes	2009-07-21	Average number of cigarettes smoked per day over the past year	13	
			Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 7	5 times using patch and 2 times using gum
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 1	Wellbutrin
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	Yes, 1	Hypnotism
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	
R5028	Yes	2009-07-14	Age subject began smoking daily	30	
			Average number of cigarettes smoked per day over the past year	20	

NOTE: Unk=Unknown.

Listing 16.2.4-4 Smoking History by Subject

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Study Population: ITT

Subject Number	Was Smoking History Collected?	Date of History Collection	Parameter	Result	Comment
R5028	Yes	2009-07-14	Has subject used smokeless tobacco in the past?	No	
			Has the subject attempted to quit with the use of NRT? If yes, how many times?	Yes, 2	Patches
			Has the subject attempted to quit with the use of pharmaceuticals other than NRTs? If yes, how many times?	Yes, 2	Chantix - once and zyban - once
			Has the subject attempted to quit with the use of other smoking cessation aids? If yes, how many times?	No	
			Has the subject made any other attempts to quit smoking? If yes, how many times?	No	

NOTE: Unk=Unknown.

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R1001	Yes	Yes	Yes
R1002	Yes	Yes	Yes
R1003	Yes	No	No
R1004	Yes	Yes	Yes
R1005	Yes	Yes	Yes
R1006	Yes	Yes	Yes
R1007	Yes	Yes	Yes
R1008	Yes	Yes	No
R1009	Yes	Yes	No
R1010	Yes	Yes	Yes
R1011	Yes	Yes	Yes

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R1012	Yes	Yes	No
R1013	Yes	Yes	Yes
R1014	Yes	No	No
R1015	Yes	Yes	Yes
R1016	Yes	Yes	Yes
R1017	Yes	Yes	Yes
R1018	Yes	Yes	No
R1019	Yes	Yes	No
R1020	Yes	Yes	Yes
R1021	Yes	No	Yes
R1022	Yes	Yes	Yes

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R1023	Yes	No	No
R1024	Yes	Yes	Yes
R1025	Yes	Yes	Yes
R1026	Yes	Yes	Yes
R1027	Yes	No	No
R1028	Yes	Yes	Yes
R1029	Yes	Yes	No
R1030	Yes	Yes	Yes
R1031	Yes	Yes	Yes
R1032	Yes	Yes	Yes
R1033	Yes	Yes	No

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R1034	Yes	Yes	Yes
R1035	Yes	Yes	Yes
R1036	Yes	Yes	No
R1037	Yes	Yes	Yes
R2001	Yes	No	No
R2002	Yes	Yes	Yes
R2003	Yes	Yes	Yes
R2004	Yes	Yes	No
R2005	Yes	Yes	Yes
R2006	Yes	Yes	No
R2007	Yes	Yes	Yes

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R2008	Yes	No	No
R2009	Yes	Yes	Yes
R2010	Yes	Yes	Yes
R2011	Yes	Yes	Yes
R2012	Yes	Yes	Yes
R2013	Yes	Yes	Yes
R2014	Yes	Yes	Yes
R2015	Yes	Yes	Yes
R2016	Yes	Yes	Yes
R2017	Yes	Yes	Yes
R2018	Yes	No	No

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R2019	Yes	Yes	Yes
R2020	Yes	Yes	No
R2021	Yes	No	Yes
R2022	Yes	Yes	No
R2023	Yes	Yes	Yes
R2024	Yes	Yes	No
R2025	Yes	Yes	No
R2026	Yes	Yes	Yes
R2027	Yes	Yes	Yes
R2028	Yes	Yes	Yes
R2029	Yes	Yes	Yes

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R2030	Yes	Yes	No
R2031	Yes	Yes	Yes
R2032	Yes	Yes	No
R3001	Yes	No	No
R3002	Yes	Yes	Yes
R3003	Yes	Yes	Yes
R3004	Yes	Yes	Yes
R3005	Yes	Yes	Yes
R3006	Yes	Yes	Yes
R3007	Yes	Yes	Yes
R3008	Yes	Yes	Yes

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R3009	Yes	Yes	No
R3010	Yes	No	Yes
R3011	Yes	Yes	Yes
R3012	Yes	No	No
R3013	Yes	Yes	Yes
R3014	Yes	Yes	No
R3015	Yes	No	No
R3016	Yes	Yes	Yes
R3017	Yes	Yes	No
R3018	Yes	Yes	No
R3019	Yes	Yes	Yes

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R3020	Yes	Yes	Yes
R3021	Yes	No	No
R3022	Yes	Yes	No
R3023	Yes	Yes	No
R3024	Yes	No	No
R3025	Yes	No	No
R3026	Yes	Yes	Yes
R3027	Yes	Yes	No
R3028	Yes	Yes	Yes
R3029	Yes	Yes	No
R3030	Yes	No	No

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R3031	Yes	Yes	No
R3032	Yes	No	No
R4001	Yes	Yes	Yes
R4002	Yes	Yes	Yes
R4003	Yes	Yes	Yes
R4004	Yes	No	No
R4005	Yes	Yes	Yes
R4006	Yes	No	No
R4007	Yes	Yes	Yes
R4008	Yes	Yes	Yes
R4009	Yes	No	Yes

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R4010	Yes	No	Yes
R4011	Yes	Yes	No
R4012	Yes	Yes	Yes
R4013	Yes	Yes	No
R4014	Yes	Yes	Yes
R4015	Yes	Yes	Yes
R4016	Yes	Yes	Yes
R4017	Yes	Yes	Yes
R4018	Yes	Yes	Yes
R4019	Yes	Yes	No
R4020	Yes	Yes	Yes

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R4021	Yes	Yes	Yes
R4022	Yes	Yes	No
R4023	Yes	Yes	Yes
R4024	Yes	Yes	No
R4025	Yes	Yes	No
R4026	Yes	Yes	Yes
R4027	Yes	Yes	Yes
R4028	Yes	Yes	Yes
R4029	Yes	Yes	Yes
R4030	Yes	Yes	No
R4031	Yes	No	No

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R4032	Yes	Yes	Yes
R4033	Yes	Yes	No
R4034	Yes	No	No
R4035	Yes	Yes	Yes
R4036	Yes	Yes	Yes
R4037	Yes	Yes	Yes
R4038	Yes	Yes	Yes
R4039	Yes	Yes	Yes
R4040	Yes	Yes	Yes
R4041	Yes	Yes	Yes
R4042	Yes	Yes	No

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R4043	Yes	Yes	No
R4044	Yes	Yes	No
R4045	Yes	Yes	Yes
R4046	Yes	Yes	No
R4047	Yes	Yes	No
R4048	Yes	Yes	No
R4049	Yes	Yes	Yes
R4050	Yes	Yes	Yes
R4051	Yes	Yes	Yes
R4052	Yes	Yes	Yes
R4053	Yes	No	No

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R4054	Yes	Yes	No
R4055	Yes	Yes	Yes
R4056	Yes	Yes	No
R4057	Yes	Yes	No
R4058	Yes	Yes	Yes
R4059	Yes	Yes	No
R4060	Yes	Yes	Yes
R4061	Yes	No	No
R4062	Yes	Yes	Yes
R4063	Yes	Yes	No
R4064	Yes	Yes	No

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R4065	Yes	Yes	No
R4066	Yes	Yes	No
R4067	Yes	Yes	No
R4068	Yes	Yes	Yes
R4069	Yes	Yes	Yes
R4070	Yes	No	Yes
R4071	Yes	Yes	Yes
R4072	Yes	Yes	Yes
R4073	Yes	No	No
R4074	Yes	Yes	No
R4075	Yes	Yes	Yes

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R4076	Yes	Yes	No
R4077	Yes	Yes	Yes
R4078	Yes	No	No
R4079	Yes	Yes	No
R4080	Yes	No	No
R4081	Yes	No	No
R4082	Yes	Yes	No
R4083	Yes	Yes	Yes
R4084	Yes	Yes	No
R4085	Yes	No	No
R4086	Yes	Yes	No

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R4087	Yes	No	No
R4088	Yes	Yes	No
R4089	Yes	Yes	No
R4090	Yes	Yes	Yes
R4091	Yes	Yes	Yes
R4092	Yes	Yes	No
R4093	Yes	Yes	Yes
R4094	Yes	Yes	Yes
R4095	Yes	No	No
R4096	Yes	Yes	Yes
R4097	Yes	Yes	Yes

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R4098	Yes	Yes	No
R4099	Yes	Yes	Yes
R4100	Yes	Yes	Yes
R4101	Yes	No	No
R4102	Yes	Yes	No
R4103	Yes	Yes	No
R4104	Yes	No	No
R4105	Yes	Yes	Yes
R4106	Yes	Yes	No
R4107	Yes	Yes	No
R4108	Yes	Yes	No

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R4109	Yes	Yes	No
R4110	Yes	No	No
R4111	Yes	No	No
R4112	Yes	Yes	No
R4113	Yes	Yes	No
R4114	Yes	Yes	Yes
R4115	Yes	Yes	No
R4116	Yes	Yes	Yes
R4117	Yes	Yes	Yes
R4118	Yes	Yes	Yes
R4119	Yes	Yes	No

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R4120	Yes	Yes	No
R4121	Yes	No	No
R5001	Yes	Yes	Yes
R5002	Yes	No	Yes
R5003	Yes	Yes	Yes
R5004	Yes	Yes	Yes
R5005	Yes	Yes	No
R5006	Yes	Yes	Yes
R5007	Yes	No	No
R5008	Yes	Yes	Yes
R5009	Yes	No	No

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R5010	Yes	Yes	No
R5011	Yes	Yes	No
R5012	Yes	No	No
R5013	Yes	Yes	Yes
R5014	Yes	Yes	No
R5015	Yes	Yes	Yes
R5016	Yes	No	No
R5017	Yes	No	No
R5018	Yes	Yes	Yes
R5019	Yes	Yes	Yes
R5020	Yes	Yes	No

Listing 16.2.4-5 Population by Subject

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Subject Number	Intention-to-Treat (ITT)	Population Compliant	Fully Evaluable
R5021	Yes	Yes	Yes
R5022	Yes	Yes	Yes
R5023	Yes	Yes	No
R5024	Yes	No	No
R5025	Yes	Yes	Yes
R5026	Yes	No	No
R5027	Yes	No	Yes
R5028	Yes	Yes	No