

DOC Code C_CT_CER_005_05	Valid from 09.03.2020	Valid until 08.06.2025	Print date 09.04.2020
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Appendix B

Data Listings

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Discontinued subjects

Listing 1: Discontinued subjects

Part 1 of 2

Center	Site ID / Screening No.	Did the subject complete the study as planned?	If no, the subject was discontinued for the following reason	If other or withdrawal by subject, please specify	Date of completion / withdrawal	Relative day to start of treatment	Any comments?
Dermatology and venerology clinic	01-003	No	WITHDRAWAL BY SUBJECT	PERSONAL REASONS	09APR2019	78	No
	01-008	No	OTHER	NO AESTHETIC EFFECT AT VISIT 7	07AUG2019	188	No
	01-009	No	OTHER	NO AESTHETIC EFFECT AT VISIT 7	07AUG2019	188	No
	01-010	No	OTHER	NO AESTHETIC EFFECT AT V8	22OCT2019	264	No
	01-017	No	OTHER	NO AESTHETIC EFFECT AT VISIT 7	22JUL2019	168	No
	01-020	No	OTHER	NO AESTHETIC EFFECT AT VISIT 7	04SEP2019	212	No
	01-021	No	OTHER	NO AESTHETIC EFFECT AT VISIT 7	07AUG2019	184	No
	01-022	No	OTHER	PATIENT SUFFERS FROM FAMILIAL CATESTROPHES (FATHER DIED AND DAUGHTER SUFFERS FROM BREAST CANCER). PATIENT WANTS TO QUIT THE STUDY.	05MAR2019	23	No
	02-022	No	OTHER	NO AESTHETIC EFFECT AT VISIT 8	02OCT2019	246	No
	02-023	No	OTHER	NO AESTHETIC EFFECT AT VISIT 8	09OCT2019	253	No

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Listing 1: Discontinued subjects

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Center	Site ID / Screening No.	Did the subject complete the study as planned?	If no, the subject was discontinued for the following reason	If other or withdrawal by subject, please specify	Date of completion / withdrawal	Relative day to start of treatment	Any comments?
Yuvel fine aesthetics	02-025	No	OTHER	COMPLETED AS PLANNED ACCORDING TO CIP SECTION 16. 75% OF SUBJECTS WITHOUT AESTHETIC EFFECT	02OCT2019	246	No
	02-027	No	OTHER	NO AESTHETIC EFFECT AT VISIT 8	10OCT2019	253	No
	02-028	No	OTHER	COMPLETED AS PLANNED ACCORDING TO CIP SECTION 16. 75% OF SUBJECTS WITHOUT AESTHETIC EFFECT	02OCT2019	245	No
	02-033	No	OTHER	NO AESTHETIC EFFECT AT VISIT 8	09OCT2019	252	No

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Protocol deviations

Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	01-001	32	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 49 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		59	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 72 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		97	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 99 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		130	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 123 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		195	Yes	DM	Visit 6: Cutometer measurement values right LCL missing due to missing record of data by program.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		373	Yes	MM (YVM)	Subject was randomized although prohibited medication was used (immunosuppressant Arava) before and during the study.	5.2. Eligibility criteria not met (but enclosed) - 2. Exclusion criteria met are specified in the description	-	Major
	01-002	17	Yes	DM	Visit 2: Visit missed.	5.5. Visit completion - 1. Missed visit	-	Major
		60	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 72 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	01-003	271	Yes	DM	Visit 3: Cutometer measurement not done for right perioral rhytids due to optimal result.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
	01-004	25	Yes	DM	Visit 2: was not done 17 to 25 days after Visit 1. The difference are 29 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		62	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 70 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		99	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 99 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		132	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 121 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		154	Yes	DM	Visit 3: injection not done for perioral rhytids due to subject decision.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Major
		155	Yes	DM	Visit 3: injection not done for right lateral canthal lines due to subject decision.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		156	Yes	DM	Visit 3: injection not done for left lateral canthal lines due to subject decision.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	01-002	98	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 98 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		131	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 126 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		158	Yes	DM	Visit 3: injection not done for perioral rhytids due to subject decision.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
	01-003	22	Yes	DM	Subject dropped out after Visit 4.	5.5. Visit completion - 1. Missed visit	-	Minor
		33	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 53 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		61	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 78 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Major
		200	Yes	DM	Visit 3: injection not done for perioral rhytids due to optimal result.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		239	Yes	CRA (VS)	Visit 2: Patient missed the visit.	5.5. Visit completion - 1. Missed visit	Clarification of the reason with PI during visit: Minor	Major

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Listing 2.1: Protocol deviations

Part 4 of 45

Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	01-004	157	Yes	DM	Visit 2: injection not done for perioral rhytids due to subject decision.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
	01-005	34	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 49 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		63	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 78 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Major
		100	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 109 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		133	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 126 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	01-006	35	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 49 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		64	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 73 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		101	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 98 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	01-006	134	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 123 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		268	Yes	DM	Visit 1: Corneometer measurement for left lateral canthal lines was not done.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		269	Yes	DM	Visit 5: Corneometer measurement for right and left lateral canthal lines missing due to problems with recording data.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
	01-007	65	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 62 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		159	Yes	DM	Visit 3: injection not done for left lateral canthal lines due to optimal aesthetic result.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		160	Yes	DM	Visit 3: injection not done for right lateral canthal lines due to optimal aesthetic result.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		161	Yes	DM	Visit 3: injection not done for perioral rhytids due to optimal aesthetic result.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		272	Yes	DM	Visit 3: Cutometer measurement missing for right perioral rhytid due to saving problems.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	01-007	364	Yes	DM	Visit 5: Cutometer measurement missing for all three test areas due to technical reasons.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
	01-008	66	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 62 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		153	Yes	DM	Visit 1: right lateral canthus photography done after IMD administration.	5.6. Assessment or time point completion - 3. Efficacy performance not properly performed	-	Major
		273	Yes	DM	Visit 6: Cutometer measurement missing for left perioral rhytids due to saving problems.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		353	Yes	CRA (ks)	Investigator did not signed and dated informed consent V 4.0 10JUL2018	5.1. Informed consent - 4. Informed consent not signed and/or dated by appropriate site staff	The informed consent was signed and dated on PV7 and confirmation was given by Prof. Kopera that she informed the subject accordingly. On 01FEB2019. Copy of the document needs to be given to subject on next visit. KS 26.9.19 copy was provided to subject.	Major
		359	Yes	CRA (ks)	Visit 7: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		368	Yes	DM	Visit 7: was not done 161 to 175 days after Visit 1. The difference are 188 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	01-009	67	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 62 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	01-009	354	Yes	CRA (ks)	Investigator did not signed and dated informed consent V2.0 10 APR2019	5.1. Informed consent - 4. Informed consent not signed and/or dated by appropriate site staff	The informed consent was signed and dated on PV7 and cofirmation was given by Prof. Kopera that sche informed the subject acc. On 27May2019. Copy of the document need to be given to subject on next visit.KS: copy was provided to subject	Major
		360	Yes	CRA (ks)	Visit 7: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		369	Yes	DM	Visit 7: was not done 161 to 175 days after Visit 1. The difference are 188 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	01-010	68	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 62 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		278	Yes	Stat	Visit 3: injection not done for perioral rhytids due to optimal result.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		363	Yes	DM	Visit 8 (optional): missing Corneometer measurement due to technical reasons for all three test areas.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		365	Yes	DM	Visit 8 (optional): missing Cutometer measurement due to technical reasons for all three test areas.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		366	Yes	DM	Visit 7 (optional): missing Corneometer values due to other reasons for all three test areas.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	01-010	367	Yes	DM	Visit 7 (optional): missing Cutometer measurement due to technical reasons for all three test areas.	5.6. Assessment or time point completion - 6. Incomplete safety assessment	-	Minor
		372	Yes	DM	Visit 8: was not done 245 to 259 days after Visit 1. The difference are 264 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	01-011	37	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 37 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		69	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 64 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		196	Yes	DM	Visit 4: missing Corneometer measurement due to technical reasons for all three test areas.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		201	Yes	DM	Visit 1: Missing values of Cutometer measurement for all three test areas.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
	01-012	38	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 37 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		70	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 64 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	01-012	197	Yes	DM	Visit 4: missing Corneometer measurement.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
	01-013	135	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 106 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		240	Yes	CRA (VS)	Visit 5: Patient missed the visit.	5.5. Visit completion - 1. Missed visit	Clarification of the reason with PI during visit: Minor	Minor
	01-014	39	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 36 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		159	Yes	DM	Visit 3: injection not done for left lateral canthal lines due to optimal result.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		160	Yes	DM	Visit 3: injection not done for right lateral canthal lines due to aesthetic result.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		161	Yes	DM	Visit 3: injection not done for perioral rhytids due to optimal result.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		202	Yes	DM	Visit 5: Missing values of Corneometer measurement for left perioral rhytids.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	01-015	20	Yes	DM	Visit 3: Visit missed.	5.5. Visit completion - 1. Missed visit	-	Major
		102	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 95 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	01-016	40	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 35 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		162	Yes	DM	Visit 2: injection not done for left lateral canthal lines due to previous Adverse event.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Major
		163	Yes	DM	Visit 2: injection not done for right lateral canthal lines due to previous Adverse event.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Major
		164	Yes	DM	Visit 2: injection not done for perioral rhytids due to previous Adverse event.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Major
		165	Yes	DM	Visit 3: injection not done for perioral rhytids due to subject decision.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Major
	01-017	71	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 64 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	01-017	166	Yes	DM	Visit 3: injection not done for left lateral canthal lines due to optimal result.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		167	Yes	DM	Visit 3: injection not done for right lateral canthal lines due to optimal result.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		168	Yes	DM	Visit 3: injection not done for perioral rhytids due to optimal result.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		205	Yes	DM	Visit 3: Missing values of Cutometer measurement for right and left perioral rhytids.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		270	Yes	DM	Visit 1: Missing values of Corneometer measurement for left perioral rhytids.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
	01-018	21	Yes	DM	Visit 3: Visit missed.	5.5. Visit completion - 1. Missed visit	-	Major
		72	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 62 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		206	Yes	DM	Visit 2: Missing values of Cutometer measurement for left lateral canthal lines.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	01-018	207	Yes	DM	Visit 5: Missing values of Cutometer measurement for all treated areas (LCL).	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
	01-019	41	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 36 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		73	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 64 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	01-020	42	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 37 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		136	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 105 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		361	Yes	CRA (ks)	Visit 7: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		370	Yes	DM	Visit 7: was not done 161 to 175 days after Visit 1. The difference are 212 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	01-021	43	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 37 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor

- : not applicable

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	01-021	137	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 105 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		362	Yes	CRA (ks)	Visit 7: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		371	Yes	DM	Visit 7: was not done 161 to 175 days after Visit 1. The difference are 184 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	01-022	19	Yes	DM	Subject dropped out after Visit 1.	5.5. Visit completion - 1. Missed visit	-	Major
	01-023	44	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 50 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		74	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 71 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		103	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 113 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		138	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 120 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	01-023	274	Yes	DM	Visit 4: Cutometer measurement missing for left perioral rhytids due to saving problems.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
	01-024	26	Yes	DM	Visit 2: was not done 17 to 25 days after Visit 1. The difference are 27 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		45	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 50 days. But IMD was done at visit day 57.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		75	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 75 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Major
		104	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 106 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		209	Yes	DM	Visit 3: device administration was done on 10-APR-2019 but all visit procedures were don on 03-APR-2019.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		210	Yes	DM	Visit 2: No corneometer measurement done due to computer problems.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
	01-025	76	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 74 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Major

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	01-025	105	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 99 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		208	Yes	DM	Visit 2: Corneometer measurements missing due to technical reasons.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
	NA	355	Yes	CRA (ks)	Informed consent process not described in the subject records in detail, only limited information (Version No., time according to worksheet)	5.1. Informed consent - 6. Other informed consent deviations	Clarification note to be provided by investigator Prof. Kopera	Minor
Yuvell fine aesthetics	02-002	1	Yes	MM	Subject received treatment with systemic corticosteroid (prednisolone 25 mg BID for 6 days) for treatment of AE during the study	5.4. Excluded, prohibited medication or non-drug therapy / treatment - 1. Medication, excluded by the protocol, was administered	-	Minor
		139	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 119 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	02-005	27	Yes	DM	Visit 2: was not done 17 to 25 days after Visit 1. The difference are 26 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		279	Yes	DM	Visit 2: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	02-006	77	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 63 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Yuvell fine aesthetics	02-006	248	Yes	CRA (VS)	Visit 2: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	A second humidifier was provided.	Minor
		332	Yes	SPON (MN)	Visit 1: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	02-007	46	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 36 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		106	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 98 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		169	Yes	DM	Visit 3: injection not done for perioral rhytids due subject decision.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Major
	02-008	107	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 92 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		170	Yes	DM	Visit 2: injection not done for left lateral canthal lines due to not necessary.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		171	Yes	DM	Visit 2: injection not done for right lateral canthal lines due to not necessary.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Yuvell fine aesthetics	02-008	172	Yes	DM	Visit 3: injection not done for left lateral canthal lines due to not necessary.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		173	Yes	DM	Visit 3: injection not done for right lateral canthal lines due to not necessary.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		333	Yes	SPON (MN)	Visit 5: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	02-009	174	Yes	DM	Visit 3: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
	02-010	175	Yes	DM	Visit 2: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		334	Yes	SPON (MN)	Visit 6: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	02-012	176	Yes	DM	Visit 3: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		335	Yes	SPON (MN)	Visit 5: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Yuvell fine aesthetics	02-013	140	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 106 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		177	Yes	DM	Visit 3: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
	02-014	280	Yes	DM	Visit 5: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		336	Yes	SPON (MN)	Visit 6: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	02-015	28	Yes	DM	Visit 2: was not done 17 to 25 days after Visit 1. The difference are 29 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		178	Yes	DM	Visit 2: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		337	Yes	SPON (MN)	Visit 6: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	02-016	179	Yes	DM	Visit 3: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Yuvell fine aesthetics	02-016	338	Yes	SPON (MN)	Visit 5 and Visit 6: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	02-017	29	Yes	DM	Visit 2: was not done 17 to 25 days after Visit 1. The difference are 28 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		180	Yes	DM	Visit 2: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		181	Yes	DM	Visit 3: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
	02-018	108	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 79 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		182	Yes	DM	Visit 2: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		281	Yes	DM	Visit 6: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		339	Yes	SPON (MN)	Visit 5: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Yuvell fine aesthetics	02-023	284	Yes	DM	Visit 6: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		343	Yes	SPON (MN)	Visit 5: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		358	Yes	CRA (ks)	Visit 7 (optional): Corneo and Cutometer humidity and temperature out of range humidity 37,2 left, 37 right, temperature 23,4°C li, 23,1°C right	5.8. Trial procedures - 8. Other deviation from trial procedures	Site is aware of the discrepancy.	Minor
	02-024	185	Yes	DM	Visit 2: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		186	Yes	DM	Visit 3: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		249	Yes	CRA (VS)	Visit 1: No usable data from corneometry measurement (right and left perioral rhytids). Error saving data in the computer.	5.6. Assessment or time point completion - 1. Missed performance assessment	Site was retrained.	Minor
		286	Yes	DM	Visit 6: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		344	Yes	SPON (MN)	Visit 5: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Yuvell fine aesthetics	02-018	356	Yes	CRA (ks)	Informed consent: the date given by the subject does not include the year. Only 24.1. is documented	5.1. Informed consent - 6. Other informed consent deviations	The site will try to ask the subject for a comment on the ICF on a next site visit, but the subject has completed the trial already.	Minor
	02-019	288	Yes	DM	Visit 6: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	02-020	340	Yes	SPON (MN)	Visit 5: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	02-021	183	Yes	DM	Visit 2: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		341	Yes	SPON (MN)	Visit 5: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	02-022	184	Yes	DM	Visit 2: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		342	Yes	SPON (MN)	Visit 5: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	02-023	211	Yes	DM	Visit 1: no corneometer values for right perioral rhytids due to technical problems.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Yuvell fine aesthetics	02-025	30	Yes	DM	Visit 2: was not done 17 to 25 days after Visit 1. The difference are 36 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		187	Yes	DM	Visit 3: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		250	Yes	CRA (VS)	Visit 1: No usable data from corneometry measurement (right and left perioral rhytids). Error saving data in the computer.	5.6. Assessment or time point completion - 1. Missed performance assessment	Site was retrained.	Minor
		251	Yes	DM	Visit 3: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		287	Yes	DM	Visit 6: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	02-026	31	Yes	DM	Visit 2: was not done 17 to 25 days after Visit 1. The difference are 28 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		141	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 119 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		294	Yes	DM	Visit 6: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Yuvell fine aesthetics	02-027	47	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 49 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		282	Yes	DM	Visit 6: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		345	Yes	SPON (MN)	Visit 5: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	02-028	48	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 49 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		188	Yes	DM	Visit 2: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		285	Yes	DM	Visit 6: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	02-029	289	Yes	DM	Visit 6: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		346	Yes	SPON (MN)	Visit 5: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Yuvell fine aesthetics	02-030	49	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 49 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		189	Yes	DM	Visit 2: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		190	Yes	DM	Visit 3: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		293	Yes	DM	Visit 6: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		347	Yes	SPON (MN)	Visit 5: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	02-031	50	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 36 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		191	Yes	DM	Visit 2: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		192	Yes	DM	Visit 3: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Yuvell fine aesthetics	02-034	194	Yes	DM	Visit 2: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		291	Yes	DM	Visit 6: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		351	Yes	SPON (MN)	Visit 1 and Visit 5: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	NA	357	Yes	CRA (ks)	Informed consent process not described in the subject records in detail, only limited information (Version No., time according to worksheet)	5.1. Informed consent - 6. Other informed consent deviations	Clarification note to be provided by investigator Dr. Sulovsky	Minor
Mara Graz	03-001	243	Yes	CRA (VS)	Visit 3: A cannula and not the needle included in the IMD kit was used at injection.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	Site was retrained.	Major
		304	Yes	DM	VISIT 5: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-002	78	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 63 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		244	Yes	CRA (VS)	Visit 3: A cannula and not the needle included in the IMD kit was used at injection.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	Site was retrained.	Major

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Yuvell fine aesthetics	02-031	290	Yes	DM	Visit 6: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		348	Yes	SPON (MN)	Visit 3: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	02-032	51	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 49 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		292	Yes	DM	Visit 6: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		349	Yes	SPON (MN)	Visit 5: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	02-033	193	Yes	DM	Visit 2: injection not done for perioral rhytids due to not necessary	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Minor
		283	Yes	DM	Visit 6: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		350	Yes	SPON (MN)	Visit 5: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor

- : not applicable

Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-002	305	Yes	DM	VISIT 5: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-003	79	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 61 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		142	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 106 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		306	Yes	DM	VISIT 6: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-004	24	Yes	DM	Visit 5: Visit missed.	5.5. Visit completion - 1. Missed visit	-	Minor
		307	Yes	DM	VISIT 6: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-005	143	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 106 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		308	Yes	DM	VISIT 2: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-005	309	Yes	DM	VISIT 6: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-006	310	Yes	DM	VISIT 3: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		311	Yes	DM	VISIT 5: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-007	109	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 75 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		229	Yes	CRA KS	Urine test performed in subject with post-menopausal status, V4-V6	5.8. Trial procedures - 8. Other deviation from trial procedures	For safety reason Dr. Rappi decided during study to perform urine test in all women, as he heard about a 70 years old pregnant women	Minor
		312	Yes	DM	VISIT 6: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-008	80	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 61 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		144	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 106 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-008	313	Yes	DM	VISIT 4: The climatic conditions were not met for corneometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-009	81	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 61 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		145	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 106 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		314	Yes	DM	VISIT 3: The climatic conditions were not met for corneometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-010	110	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 75 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	03-011	2	Yes	DM	Visit 2: No clinical photography done for canthal lines due to Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		3	Yes	DM	Visit 2: No device administration at canthal lines due previous Adverse Event	5.7. Wrong study treatment/administration/dose - 8. Other deviations related to wrong study treatment/administration/dose	-	Minor
		4	Yes	DM	Visit 2: No corneometer measurement done for canthal lines due to Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-011	256	Yes	DM	Visit 3: No corneometer measurement done for canthal lines due to Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		257	Yes	DM	Visit 4: No corneometer measurement done for canthal lines due to Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		258	Yes	DM	Visit 5: No corneometer measurement done for canthal lines due to Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		259	Yes	DM	Visit 6: No corneometer measurement done for canthal lines due to Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		260	Yes	DM	Visit 3: No cutometer measurement done for canthal lines due to Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		261	Yes	DM	Visit 4: No cutometer measurement done for canthal lines due to Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		262	Yes	DM	Visit 5: No cutometer measurement done for canthal lines due to Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		263	Yes	DM	Visit 6: No cutometer measurement done for canthal lines due to Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-011	5	Yes	DM	Visit 2: No cutometer measurement done for canthal lines due to Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		11	Yes	DM	Visit 3: No administration of canthal lines done - not wanted.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Major
		245	Yes	CRA (VS)	Visit 3: A cannula and not the needle included in the IMD kit was used at injection.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	Site was retrained.	Major
		246	Yes	CRA (VS)	Visit 2: A cannula and not the needle included in the IMD kit was used at injection.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	Site was retrained.	Major
		252	Yes	DM	Visit 3: No clinical photography done for canthal lines due to no treatment wanted.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		253	Yes	DM	Visit 4: No clinical photography done for canthal lines - not wanted.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		254	Yes	DM	Visit 5: No clinical photography done for canthal lines.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		255	Yes	DM	Visit 6: No clinical photography done for canthal lines.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-013	316	Yes	DM	VISIT 2: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		317	Yes	DM	VISIT 4: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-014	12	Yes	DM	Visit 2: Cannula was used for device administration (cannula type technique= linear threading) of lower lip and multipuncture of upper lip.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Major
		13	Yes	DM	Visit 3: Cannula (cannula type technique= linear threading) was used for device administration of perioral rhytids.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Major
		111	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 79 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		233	Yes	DM	Visit 4: Photos were done 5 days after IMD. Photos done 26JAN2019 and visit were done 21JAN2019.	5.6. Assessment or time point completion - 4. Out of window efficacy performance	-	Major
		318	Yes	DM	VISIT 4: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		319	Yes	DM	VISIT 5: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-011	264	Yes	DM	Visit 3: No Global Aesthetic Improvement by investigator done for canthal lines.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		265	Yes	DM	Visit 4: No Global Aesthetic Improvement by investigator done for canthal lines.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		266	Yes	DM	Visit 5: No Global Aesthetic Improvement by investigator done for canthal lines.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		267	Yes	DM	Visit 6: No Global Aesthetic Improvement by investigator done for canthal lines.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		315	Yes	DM	VISIT 5: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-012	82	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 61 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		146	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 106 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	03-013	83	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 62 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-015	112	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 79 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	03-016	84	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 61 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		320	Yes	DM	VISIT 2: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-017	85	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 61 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		147	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 106 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		321	Yes	DM	VISIT 6: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-018	113	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 75 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	03-019	114	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 74 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-019	199	Yes	DM	Visit 1: Corneometer and Cutometer measurements were done besides no IMD administration was done later at this visit.	5.6. Assessment or time point completion - 3. Efficacy performance not properly performed	-	Minor
		230	Yes	CRA KS	Urine test performed in subject with post-menopausal status, V4+5	5.8. Trial procedures - 8. Other deviation from trial procedures	For safety reason Dr. Rappi decided during study to perform urine test in all women, as he heard about a 70 years old pregnant women	Minor
		322	Yes	DM	VISIT 4: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-020	6	Yes	DM	Visit 2: No clinical photography done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		7	Yes	DM	Visit 2: No device administration at canthal lines due previous Adverse Event	5.7. Wrong study treatment/administration/dose - 8. Other deviations related to wrong study treatment/administration/dose	-	Minor
		8	Yes	DM	Visit 2: No corneometer measurement done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		9	Yes	DM	Visit 2: No cutometer measurement done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		212	Yes	DM	Visit 3: No clinical photography done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-020	213	Yes	DM	Visit 3: No Global Aesthetic Improvement by investigator done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		214	Yes	DM	Visit 3: No device administration at canthal lines due to previous Adverse Event.	5.7. Wrong study treatment/administration/dose - 8. Other deviations related to wrong study treatment/administration/dose	-	Minor
		215	Yes	DM	Visit 3: No corneometer measurement done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		216	Yes	DM	Visit 3: No cutometer measurement done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		217	Yes	DM	Visit 4: No clinical photography done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		218	Yes	DM	Visit 4: No Global Aesthetic Improvement by investigator done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		219	Yes	DM	Visit 4: No corneometer measurement done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		220	Yes	DM	Visit 4: No cutometer measurement done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor

- : not applicable

Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-020	221	Yes	DM	Visit 5: No clinical photography done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		222	Yes	DM	Visit 5: No Global Aesthetic Improvement by investigator done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		223	Yes	DM	Visit 5: No corneometer measurement done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		224	Yes	DM	Visit 5: No cutometer measurement done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		225	Yes	DM	Visit 6: No clinical photography done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		226	Yes	DM	Visit 6: No Global Aesthetic Improvement by investigator done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		227	Yes	DM	Visit 6: No corneometer measurement done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor
		228	Yes	DM	Visit 6: No cutometer measurement done for canthal lines due to previous Adverse Event.	5.6. Assessment or time point completion - 2. Incomplete performance assessment	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-020	323	Yes	DM	VISIT 4: The climatic conditions were not met for cotometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		324	Yes	DM	VISIT 5: The climatic conditions were not met for cotometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-021	115	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 75 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	03-022	86	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 61 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		148	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 106 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	03-023	231	Yes	CRA KS	Urine test performed in subject with post-menopausal status, V1-6	5.8. Trial procedures - 8. Other deviation from trial procedures	For safety reason Dr. Rappi decided during study to perform urine test in all women, as he heard about a 70 years old pregnant women	Minor
		234	Yes	DM	Visit 4: Photos were done 5 days after IMD. Photos done 26JAN2019 and visit were done 21JAN2019.	5.6. Assessment or time point completion - 4. Out of window efficacy performance	-	Major
		325	Yes	DM	VISIT 2: The climatic conditions were not met for cotometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-023	326	Yes	DM	VISIT 3: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		327	Yes	DM	VISIT 4: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-024	116	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 75 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	03-025	87	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 61 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		149	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 106 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		328	Yes	DM	VISIT 4: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-026	117	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 75 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		232	Yes	CRA KS	Urine test performed in subject with post- menopausal status, V1, V5, V6	5.8. Trial procedures - 8. Other deviation from trial procedures	For safety reason Dr. Rappl decided during study to perform urine test in all women, as he heard about a 70 years old pregnant women	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-027	118	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 75 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	03-028	88	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 61 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		150	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 106 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	03-029	89	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 61 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		119	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 106 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	03-030	90	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 61 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		151	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 106 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	03-031	120	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 79 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-031	329	Yes	DM	VISIT 4: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-032	91	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 61 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		152	Yes	DM	Visit 6: was not done 108 to 116 days after Visit 1. The difference are 106 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	03-033	16	Yes	DM	Visit 3: Cannula was used for device administration.	5.7. Wrong study treatment/administration/dose - 1. Study treatment not administered per protocol	-	Major
		52	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 36 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		92	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 51 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		121	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 78 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		330	Yes	DM	VISIT 2: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-033	331	Yes	DM	VISIT 4: The climatic conditions were not met for corneometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-034	53	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 37 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		122	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 79 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		295	Yes	DM	VISIT 4: The climatic conditions were not met for corneometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		296	Yes	DM	VISIT 2: The climatic conditions were not met for corneometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-035	54	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 36 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		93	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 51 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		123	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 78 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-039	95	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 51 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		125	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 78 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		301	Yes	DM	VISIT 2: The climatic conditions were not met for cutometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-040	126	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 79 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	03-041	57	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 37 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		127	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 79 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
	03-042	96	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 61 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		128	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 106 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-035	297	Yes	DM	VISIT 6: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		298	Yes	DM	VISIT 2: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
		299	Yes	DM	VISIT 1: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-036	55	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 36 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		94	Yes	DM	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 51 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		124	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 78 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		300	Yes	DM	VISIT 6: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-039	56	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 36 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor

- : not applicable

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Listing 2.1: Protocol deviations

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Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-042	302	Yes	DM	VISIT 5: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	03-043	58	Yes	DM	Visit 3: was not done 38 to 46 days after Visit 1. The difference are 37 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		129	Yes	DM	Visit 5: was not done 80 to 88 days after Visit 1. The difference are 78 days.	5.5. Visit completion - 2. Out of window visit/phone contact	-	Minor
		303	Yes	DM	VISIT 1: The climatic conditions were not met for autometer and corneometer measurement.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor
	NA	352	Yes	CRA (BC)	IMD label were not stick in the source data of patients in all cases.	5.8. Trial procedures - 8. Other deviation from trial procedures	-	Minor

- : not applicable

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Listing 2.2: Study deviations

Part 1 of 8

Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-010	2	Yes	PM (FE)	Visit 5: Forgery of the visit appointment. Some visit data and results were entered before Visit was done. Login data of Mr. Rappl were provided to Ms Cuno for data entry.	-	Report to the authority.	Major
	03-014	3	Yes	PM (FE)	Visit 5: Forgery of the visit appointment. Some visit data and results were entered before Visit was done. Login data of Mr. Rappl were provided to Ms Cuno for data entry.	-	Report to the authority.	Major
	03-018	4	Yes	PM (FE)	Visit 5: Forgery of the visit appointment. Some visit data and results were entered before Visit was done. Login data of Mr. Rappl were provided to Ms Cuno for data entry.	-	Report to the authority.	Major
	03-019	5	Yes	PM (FE)	Visit 5: Forgery of the visit appointment. Some visit data and results were entered before Visit was done. Login data of Mr. Rappl were provided to Ms Cuno for data entry.	-	Report to the authority.	Major
	NA	1	Yes	CRA KS	Same time of assessments e.g. photo and corneo (few cases also cutameter) or ICF and urine sample collection	-	Comment by K.Scheel: clarification with Dr. Rappl and IC given time was documented and the delivery	Minor

- : not applicable

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Listing 2.2: Study deviations

Part 3 of 8

Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-001-03-043	14	yes	CRA	Patients were not screened as per final CIP: in ascending order. Recruitment was initially done by word of mouth and the subjects contacted the site. In order to organize the subject visits as per regard to vacation and working times of the subjects) he and his team have organized the subjects individually, for this subject numbers were not assigned in ascending order as per protocol. PD was documented previously. PI confirmed that no pre-screening was done.	-	-	Minor
	03-007	11	Yes	PM (FE)	Visit 5: Forgery of the visit appointment. Some visit data and results were entered before Visit was done. Login data of Mr. Rappl were provided to Ms Cuno for data entry.	-	Report to the authority.	Major
	03-031	12	Yes	PM (FE)	Visit 2: Forgery of the visit appointment. Some visit data and results were entered before Visit was done. Login data of Mr. Rappl were provided to Ms Cuno for data entry.	-	Report to the authority.	Major
	NA	13	No	CRA	Inclusion of 13 subjects during on day (ICF process and sample time)	-	-	-
		15	No	CRA (VS)	Upload photos to the foto-portal Quantificare.	The photos of the visits were loaded late on the foto-portal of Quantificare.	-	-

- : not applicable

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Listing 2.2: Study deviations

Part 2 of 8

Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Mara Graz	03-015	10	Yes	PM (FE)	Visit 5: Forgery of the visit appointment. Some visit data and results were entered before Visit was done. Login data of Mr. Rappl were provided to Ms Cuno for data entry.	-	Report to the authority.	Major
	03-021	6	Yes	PM (FE)	Visit 5: Forgery of the visit appointment. Some visit data and results were entered before Visit was done. Login data of Mr. Rappl were provided to Ms Cuno for data entry.	-	Report to the authority.	Major
	03-024	7	Yes	PM (FE)	Visit 5: Forgery of the visit appointment. Some visit data and results were entered before Visit was done. Login data of Mr. Rappl were provided to Ms Cuno for data entry.	-	Report to the authority.	Major
	03-026	8	Yes	PM (FE)	Visit 5: Forgery of the visit appointment. Some visit data and results were entered before Visit was done. Login data of Mr. Rappl were provided to Ms Cuno for data entry.	-	Report to the authority.	Major
	03-027	9	Yes	PM (FE)	Visit 5: Forgery of the visit appointment. Some visit data and results were entered before Visit was done. Login data of Mr. Rappl were provided to Ms Cuno for data entry.	-	Report to the authority.	Major

- : not applicable

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Listing 2.2: Study deviations

Part 4 of 8

Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	NA	20	No	CRA (KS)	Site has only one investigator at the site from 1st July 2019 until PV 7 (31.7.2019) .	6. Study deviation (StD) categorization - 6. SOP deviation	Beginning August 2019 new investigator Dr. Schug approved by EC confirmed by CTM. Post monitoring: A	-
Mara Graz	NA	16	No	CRA (VS)	Preparation of measuring and procedure room.	The air conditioner and humidifier were not activated sufficiently before the procedure started.	-	-
		17	Yes	CRA (BC)	During the verification (visit confirmation vs. initial ICF signature subject) it was noted that the dates of ICF signatures of most of the subjects at the site were not handwritten by subject independently, but documented by someone else responsible at the site. This is not clearly traceable.	-	-	Minor
		18	Yes	CRA (BC)	During this visit it was noted that the screening number of the subjects was not documented correctly at site for most of the subjects. Dr. Rappi was informed that site number is 03 and the subsequent subjects should have been correctly numbered as the following: e.g. subject number one: 03-001, 03-043, a clarification note should be written as well as a PD to be documented for this issue.	-	-	Minor
		19	Yes	CRA (BC)	At the end of each page of the worksheet signature, date and time should be documented. There are cases for which the time is earlier as the end time e.g. often on device administration page. Here he entered the time of the start of the assessment. Dr. Rappi confirmed that date and time was entered by Mrs. Cuno and he signed the forms and that time documentation was not consequently at the end of the assessment documented on the page.	-	-	Minor

- : not applicable

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Listing 2.2: Study deviations

Part 5 of 8

Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	01-010	24	Yes	CRA (KS)	Cutometry performed, but due to technical reason system did not accept probe	6. Study deviation (StD) categorization - 2. Deviations regarding corneometer / cutometer devices	Croma was already previously informed by PI as other cases were already reported by site to croma.	Minor
	01-107	25	Yes	CRA (KS)	Worksheets signed and completed not on visit date V7 in timely manner, Signed 26.7.19 visit 22.7.19	6. Study deviation (StD) categorization - 6. SOP deviation	Site was informed that the signature on the worksheet and date is for person to perform directly aft	Minor
	NA	21	Yes	CRA (KS)	Training documentation not completed (GCPcertificates site , training logs) and staff delegated before training completed for site staff. Training of Dr. Schaunig is missing:	6. Study deviation (StD) categorization - 6. SOP deviation	Availability of documents to be clarified.	Minor
		22	No	CRA (KS)	Investigator site file: documentation not completely filled and and logs not completed during trial conduct: enrolment log, identification log, drug account log, inventory log.	6. Study deviation (StD) categorization - 6. SOP deviation	Forms were completed and missing documents are filed or requested for filing/ completion into IF	-
		23	Yes	CRA (KS)	DCF's Quantificare not answered in a timely manner	6. Study deviation (StD) categorization - 6. SOP deviation	Answers of queries was requested until week 32	Minor

- : not applicable

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Listing 2.2: Study deviations

Part 7 of 8

Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	NA	34	Yes	CRA (ks)	Dr. Schug has not GCP training at start at the site.	Other	-	Minor
Yuvell fine aesthetics	NA	31	Yes	CRA (ks)	Used equipment not same time set up: Time on file name for photo has discrepancy to time documented in worksheet.	6. Study deviation (StD) categorization - 3. Deviations regarding photography device	The site was informed consider summer/ winter time in the set up of used equipment. The site document	Minor
		32	Yes	CRA (ks)	Site staff MS Garbner not delegated on delegation log before tasks performed	Other	Delegation log to be completed retrospectively, training documentation of Ms Gabner available for pr	Minor
		33	Yes	CRA (ks)	Manual temp log was not completed by site according to IMD instruction	Other	NA	Minor
		35	No	CRA (ks)	Temperature deviation 16.1.2019, 9:26 27,2°C at receipt of IMD, release by sponsor available	Other	Released by sponsor	Minor

- : not applicable

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Listing 2.2: Study deviations

Part 8 of 8

Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Yuvell fine aesthetics	NA	36	No	CRA (ks)	Temperature deviation 2./3.3.2019, 25,4°C during IMD storage (reporting on 5.3.2019, release by sponsor available	Other	Released by sponsor, reporting on 5.3.2019 as site staff was not in the office on 4.3.2019	Minor

- : not applicable

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Listing 2.2: Study deviations

Part 6 of 8

Center	Site ID / Screening No.	Unique deviation ID	Is the PD still valid/applicable?	Department	PD description	PD category - subcategory	Comment	Classification
Dermatology and venerology clinic	NA	26	Yes	CRA (BC)	Print outs of temp logger (12DEC2018-12DEC2018, 22Jan2019-05Feb2019, 26Feb2019-31Jul2019) were signed and dated by Prof. Kopera not in timely manner. Signed on 31Jul2019 instead of day of print out to confirm no deviation.	6. Study deviation (StD) categorization - 6. SOP deviation	Singed on PV 7 by Prof. Kopera	Minor
		27	Yes	CRA (BC)	Temperature control gaps: 12Dec2018 - 22Jan2019 and 05Feb2019 - 26Feb2019; no print out/read out of electronic temperature control available at site .	6. Study deviation (StD) categorization - 6. SOP deviation	None	Minor
		28	Yes	CRA (BC)	The only manual temperature documentation is available for the timeframe: 12Dec2018 - 16Jan2019. A manual temperature control from 17 Jan2019 until 03Apr2019 is not available.	6. Study deviation (StD) categorization - 6. SOP deviation	A clarification note should be provided by Prof. Kopera.	Minor
		29	Yes	CRA (ks)	Worksheets not signed by person who performed assessments. Signed by Mr. Kopera who not performed assessment.	6. Study deviation (StD) categorization - 6. SOP deviation	Worksheets to be signed by Prof. Kopera and clarification note to be provided by investigator Prof.	Minor
		30	No	CRA (ks)	Protocol Version 1.0 signed before version was finalized.	6. Study deviation (StD) categorization - 6. SOP deviation	None	-

- : not applicable

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Analysis populations

Listing 3: Subjects excluded from the analysis populations

Part 1 of 10

Center	Site ID / Screening No.	Safety Population Flag	Full Analysis Set Population Flag	Per-Protocol Population Flag	Exclusion reason	Description
Dermatology and venerology clinic	01-001	Yes	Yes	Yes	-	-
	01-002	Yes	Yes	No	Subject with protocol deviation interfering with the evaluation for GAIS at Week 8 (Visit 4)	Visit 2 missed [LCL & PR] Visit 3: injection not done for perioral rhytids due to subject decision.
	01-003	Yes	Yes	No	Subject with protocol deviation interfering with the evaluation for GAIS at Week 8 (Visit 4)	Visit 2 missed, Visit 3 injection not done for perioral rhytids due to optimal result. Visit 4 was not done 52 to 60 days after Visit 1. The difference are 78 days. Subject withdrawal after Visit 4.
	01-004	Yes	Yes	No	Subject with protocol deviation interfering with the evaluation for GAIS at Week 8 (Visit 4)	Visit 2: No injections done for perioral rhytids due to subject decision. Visit 3: No injections done due to subject decision. [LCL & PR]
	01-005	Yes	Yes	No	Subject with protocol deviation interfering with the evaluation for GAIS at Week 8 (Visit 4)	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 78 days.
	01-006	Yes	Yes	Yes	-	-
	01-007	Yes	Yes	Yes	-	Visit 3: No injections done due to optimal aesthetic result [LCL & PR]
	01-008	Yes	Yes	No	Subject with protocol deviation interfering with the evaluation for GAIS at Week 8 (Visit 4)	Visit 1: Right lateral canthus photography done after IMD administration. Visit 7: Autometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	01-009	Yes	Yes	Yes	-	Visit 7: Autometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	01-010	Yes	Yes	Yes	-	Visit 3: injection not done for perioral rhytids due to optimal result. [for LCL injection as planned in CIP]
	01-011	Yes	Yes	Yes	-	-

- : not applicable

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Listing 3: Subjects excluded from the analysis populations

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Center	Site ID / Screening No.	Safety Population Flag	Full Analysis Set Population Flag	Per-Protocol Population Flag	Exclusion reason	Description
Dermatology and venerology clinic	01-012	Yes	Yes	Yes	-	-
	01-013	Yes	Yes	Yes	-	-
	01-014	Yes	Yes	Yes	-	Visit 3: No injections done due to optimal result. [LCL & PR]
	01-015	Yes	Yes	No	Subject with protocol deviation interfering with the evaluation for GAIS at Week 8 (Visit 4)	Visit 3: Patient missed the visit.
	01-016	Yes	Yes	No	Subject with protocol deviation interfering with the evaluation for GAIS at Week 8 (Visit 4)	Visit 2: No device administration due adverse event at Visit 1. [LCL & PR] Visit 3: injection not done for perioral rhytids due to subject decision.
	01-017	Yes	Yes	Yes	-	Visit 3: injections not done due to optimal result. [LCL & PR]
	01-018	Yes	Yes	No	Subject with protocol deviation interfering with the evaluation for GAIS at Week 8 (Visit 4)	Visit 3: Visit missed.
	01-019	Yes	Yes	Yes	-	-
	01-020	Yes	Yes	Yes	-	Visit 7: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	01-021	Yes	Yes	Yes	-	Visit 7: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	01-022	Yes	No	No	Other	Subject dropped out after Visit 1.

- : not applicable

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Listing 3: Subjects excluded from the analysis populations

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Center	Site ID / Screening No.	Safety Population Flag	Full Analysis Set Population Flag	Per-Protocol Population Flag	Exclusion reason	Description
Dermatology and venerology clinic	01-023	Yes	Yes	Yes	-	Visit 4: Photos were done 5 days after IMD. Photos done 26JAN2019 and visit were done 21JAN2019.
	01-024	Yes	Yes	No	Subject with protocol deviation interfering with the evaluation for GAIS at Week 8 (Visit 4)	Visit 3: device administration was done on 10-APR-2019 but all visit procedures were done on 03-APR-2019. Visit 4: was not done 52 to 60 days after Visit 1. The difference are 75 days.
	01-025	Yes	Yes	No	Subject with protocol deviation interfering with the evaluation for GAIS at Week 8 (Visit 4)	Visit 4: was not done 52 to 60 days after Visit 1. The difference are 74 days.
Yuvell fine aesthetics	02-001	Yes	Yes	Yes	-	-
	02-002	Yes	Yes	Yes	-	Subject received treatment with systemic corticosteroid (prednisolone 25 mg BID for 6 days) for treatment of AE during the study
	02-003	Yes	Yes	Yes	-	-
	02-004	Yes	Yes	Yes	-	-
	02-005	Yes	Yes	Yes	-	Visit 2: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-006	Yes	Yes	Yes	-	Visit 1, Visit 2: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-007	Yes	Yes	No	Subject with protocol deviation interfering with the evaluation for GAIS at Week 8 (Visit 4)	Visit 3: injection not done for perioral rhytids due to subject decision.
	02-008	Yes	Yes	Yes	-	Visit 2, Visit 3: injections not done for canthal lines due to not necessary. [only LCL treated]. Visit 5: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.

- : not applicable

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Listing 3: Subjects excluded from the analysis populations

Part 4 of 10

Center	Site ID / Screening No.	Safety Population Flag	Full Analysis Set Population Flag	Per-Protocol Population Flag	Exclusion reason	Description
Yuwell fine aesthetics	02-009	Yes	Yes	Yes	-	Visit 3: injection not done for perioral rhytids due to not necessary [only PR treated]
	02-010	Yes	Yes	Yes	-	Visit 2: injection not done for perioral rhytids due to not necessary [only PR treated]. Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-011	Yes	Yes	Yes	-	-
	02-012	Yes	Yes	Yes	-	Visit 3: injection not done for perioral rhytids due to not necessary [only PR treated]. Visit 5: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-013	Yes	Yes	Yes	-	Visit 3: injection not done for perioral rhytids due to not necessary [only PR treated].
	02-014	Yes	Yes	Yes	-	Visit 5, Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-015	Yes	Yes	Yes	-	Visit 2: injection not done for perioral rhytids due to not necessary [only PR treated]. Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-016	Yes	Yes	Yes	-	Visit 3: injection not done for perioral rhytids due to not necessary [only PR treated]. Visit 5, Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-017	Yes	Yes	Yes	-	Visit 2, Visit 3: injection not done for perioral rhytids due to not necessary [only PR treated].
	02-018	Yes	Yes	Yes	-	Visit 2: injection not done for perioral rhytids due to not necessary [only PR treated]. Visit 5, Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-019	Yes	Yes	Yes	-	Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.

- : not applicable

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Listing 3: Subjects excluded from the analysis populations

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Center	Site ID / Screening No.	Safety Population Flag	Full Analysis Set Population Flag	Per-Protocol Population Flag	Exclusion reason	Description
Yuvell fine aesthetics	02-031	Yes	Yes	Yes	-	Visit 2, Visit 3: injection not done for perioral rhytids due to not necessary [only PR treated]. Visit 3, Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-032	Yes	Yes	Yes	-	Visit 5, Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-033	Yes	Yes	Yes	-	Visit 2: injection not done for perioral rhytids due to not necessary [only PR treated]. Visit 5, Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-034	Yes	Yes	Yes	-	Visit 2: injection not done for perioral rhytids due to not necessary [only PR treated]. Visit 1, Visit 5, Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
Mara Graz	03-001	No	No	No	Subject at site with inspection findings	Visit 3: Cannula was used for device administration. Visit 5: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-002	No	No	No	Subject at site with inspection findings	Visit 3: Cannula was used for device administration. Visit 5: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-003	No	No	No	Subject at site with inspection findings	Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-004	No	No	No	Subject at site with inspection findings	Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-005	No	No	No	Subject at site with inspection findings	Visit 2, Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-006	No	No	No	Subject at site with inspection findings	Visit 3, Visit 5: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-007	No	No	No	Subject at site with inspection findings	Visit 5: Invalid for statistical analysis of VCS due to study deviation. Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.

- : not applicable

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Listing 3: Subjects excluded from the analysis populations

Part 5 of 10

Center	Site ID / Screening No.	Safety Population Flag	Full Analysis Set Population Flag	Per-Protocol Population Flag	Exclusion reason	Description
Yuwell fine aesthetics	02-020	Yes	Yes	Yes	-	Visit 5: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-021	Yes	Yes	Yes	-	Visit 2: injection not done for perioral rhytids due to not necessary [only PR treated]. Visit 5: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-022	Yes	Yes	Yes	-	Visit 2: injection not done for perioral rhytids due to not necessary [only PR treated]. Visit 5: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-023	Yes	Yes	Yes	-	Visit 5, Visit 6, Visit 7: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-024	Yes	Yes	Yes	-	Visit 2, Visit 3: injection not done for perioral rhytids due to not necessary [only PR treated]. Visit 5, Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-025	Yes	Yes	Yes	-	Visit 3: injection not done for perioral rhytids due to not necessary [only PR treated]. Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-026	Yes	Yes	Yes	-	Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-027	Yes	Yes	Yes	-	Visit 5, Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-028	Yes	Yes	Yes	-	Visit 2: injection not done for perioral rhytids due to not necessary [only PR treated]. Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-029	Yes	Yes	Yes	-	Visit 5, Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	02-030	Yes	Yes	Yes	-	Visit 2, Visit 3: injection not done for perioral rhytids due to not necessary [only PR treated]. Visit 5, Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.

- : not applicable

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Listing 3: Subjects excluded from the analysis populations

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Center	Site ID / Screening No.	Safety Population Flag	Full Analysis Set Population Flag	Per-Protocol Population Flag	Exclusion reason	Description
Mara Graz	03-008	No	No	No	Subject at site with inspection findings	Visit 4: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-009	No	No	No	Subject at site with inspection findings	Visit 3: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-010	No	No	No	Subject at site with inspection findings	Visit 5: Invalid for statistical analysis of VCS due to study deviation
	03-011	No	No	No	Subject at site with inspection findings	Visit 2, Visit 3: A cannula and not the needle included in the IMD kit was used at injection. Visit 2: No administration of canthal lines due to previous AE. Visit 3: No administration of canthal lines done - not wanted. Visit 4: No Global Aesthetic Improvement by investigator done for canthal lines. Visit 5: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-012	No	No	No	Subject at site with inspection findings	-
	03-013	No	No	No	Subject at site with inspection findings	Visit 2, Visit 4: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-014	No	No	No	Subject at site with inspection findings	Visit 3: Cannula was used for device administration. Visit 4: Photos were done 5 days after IMD. Photos done 26JAN2019 and visit were done 21JAN2019. Visit 5: Invalid for statistical analysis of VCS due to study deviation. Visit 4, Visit 5: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-015	No	No	No	Subject at site with inspection findings	Visit 5: Invalid for statistical analysis of VCS due to study deviation
	03-016	No	No	No	Subject at site with inspection findings	Visit 2: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-017	No	No	No	Subject at site with inspection findings	Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-018	No	No	No	Subject at site with inspection findings	Visit 5: Invalid for statistical analysis of VCS due to study deviation

- : not applicable

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Listing 3: Subjects excluded from the analysis populations

Part 8 of 10

Center	Site ID / Screening No.	Safety Population Flag	Full Analysis Set Population Flag	Per-Protocol Population Flag	Exclusion reason	Description
Mara Graz	03-019	No	No	No	Subject at site with inspection findings	Visit 5: Invalid for statistical analysis of VCS due to study deviation. Visit 4: Autometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-020	No	No	No	Subject at site with inspection findings	Visit 2: No device administration at canthal lines due previous AEVisit 4: No Global Aesthetic Improvement by investigator done for canthal lines due to previous AE[Procedures and assessments for PR according CIP] Visit 4: Visit 5: Autometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-021	No	No	No	Subject at site with inspection findings	Visit 5: Invalid for statistical analysis of VCS due to study deviation
	03-022	No	No	No	Subject at site with inspection findings	-
	03-023	No	No	No	Subject at site with inspection findings	Visit 4: Photos were done 5 days after IMD. Photos done 26JAN2019 and visit were done 21JAN2019.Visit 2, Visit 3, Visit 4: Autometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-024	No	No	No	Subject at site with inspection findings	Visit 5: Invalid for statistical analysis of VCS due to study deviation
	03-025	No	No	No	Subject at site with inspection findings	Visit 4: Autometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-026	No	No	No	Subject at site with inspection findings	Visit 5: Invalid for statistical analysis of VCS due to study deviation
	03-027	No	No	No	Subject at site with inspection findings	Visit 5: Invalid for statistical analysis of VCS due to study deviation
	03-028	No	No	No	Subject at site with inspection findings	-
	03-029	No	No	No	Subject at site with inspection findings	-

- : not applicable

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Listing 3: Subjects excluded from the analysis populations

Part 10 of 10

Center	Site ID / Screening No.	Safety Population Flag	Full Analysis Set Population Flag	Per-Protocol Population Flag	Exclusion reason	Description
Mara Graz	03-041	No	No	No	Subject at site with inspection findings	-
	03-042	No	No	No	Subject at site with inspection findings	Visit 5: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-043	No	No	No	Subject at site with inspection findings	Visit 1: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.

- : not applicable

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Listing 3: Subjects excluded from the analysis populations

Part 9 of 10

Center	Site ID / Screening No.	Safety Population Flag	Full Analysis Set Population Flag	Per-Protocol Population Flag	Exclusion reason	Description
Mara Graz	03-030	No	No	No	Subject at site with inspection findings	-
	03-031	No	No	No	Subject at site with inspection findings	Visit 2: Invalid for statistical analysis of VCS due to study deviation Visit 4: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-032	No	No	No	Subject at site with inspection findings	-
	03-033	No	No	No	Subject at site with inspection findings	Visit 3: Cannula was used for device administration. Visit 2, Visit 4: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-034	No	No	No	Subject at site with inspection findings	Visit 2, Visit 4: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-035	No	No	No	Subject at site with inspection findings	Visit 1, Visit 2, Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-036	No	No	No	Subject at site with inspection findings	Visit 6: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-037	No	No	No	Subject at site with inspection findings	-
	03-038	No	No	No	Subject at site with inspection findings	-
	03-039	No	No	No	Subject at site with inspection findings	Visit 2: Cutometer and corneometer measurement invalid for statistical analysis of VCS due to deviation from required climatic conditions.
	03-040	No	No	No	Subject at site with inspection findings	-

- : not applicable

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Demographic data

Listing 4: Subject demographic information

Part 1 of 3

Center	Site ID / Screening No.	Year of birth	Gender	Race	Race other, specify
Dermatology and venerology clinic	01-001	1959	Female	White	-
	01-002	1963	Female	White	-
	01-003	1959	Female	White	-
	01-004	1972	Female	White	-
	01-005	1965	Female	White	-
	01-006	1970	Female	White	-
	01-007	1970	Female	White	-
	01-008	1962	Female	White	-
	01-009	1969	Female	White	-
	01-010	1982	Female	White	-
	01-011	1961	Female	White	-
	01-012	1963	Female	White	-
	01-013	1969	Female	White	-
	01-014	1964	Female	White	-
	01-015	1959	Female	White	-
	01-016	1971	Female	White	-
	01-017	1965	Female	White	-
	01-018	1965	Female	White	-
	01-019	1971	Female	White	-
	01-020	1967	Female	White	-
	01-021	1977	Female	White	-
	01-022	1964	Female	White	-
	01-023	1960	Female	White	-
	01-024	1977	Female	White	-
	01-025	1961	Female	White	-
Yuvell fine aesthetics	02-001	1978	Female	White	-
	02-002	1965	Female	White	-
	02-003	1956	Female	White	-
	02-004	1956	Female	White	-
	02-005	1963	Female	White	-
	02-006	1977	Female	White	-
	02-007	1961	Female	White	-
	02-008	1973	Female	White	-
	02-009	1946	Female	White	-
	02-010	1954	Female	White	-
	02-011	1980	Female	White	-
	02-012	1971	Female	White	-
	02-013	1966	Female	White	-
	02-014	1962	Female	White	-
	02-015	1941	Female	White	-
	02-016	1963	Female	White	-
	02-017	1964	Female	White	-
	02-018	1961	Female	White	-
	02-019	1975	Female	White	-
	02-020	1971	Female	White	-

- : not applicable

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Listing 4: Subject demographic information

Part 2 of 3

Center	Site ID / Screening No.	Year of birth	Gender	Race	Race other, specify
Yuvell fine aesthetics	02-021	1959	Female	White	-
	02-022	1965	Female	White	-
	02-023	1968	Female	White	-
	02-024	1950	Female	White	-
	02-025	1967	Female	White	-
	02-026	1990	Female	White	-
	02-027	1966	Female	White	-
	02-028	1953	Female	White	-
	02-029	1947	Female	White	-
	02-030	1969	Female	White	-
	02-031	1970	Female	White	-
	02-032	1967	Female	White	-
	02-033	1959	Female	White	-
	02-034	1981	Female	White	-
Mara Graz	03-001	1971	Female	White	-
	03-002	1968	Female	White	-
	03-003	1968	Female	White	-
	03-004	1947	Female	White	-
	03-005	1975	Female	White	-
	03-006	1971	Female	White	-
	03-007	1960	Female	White	-
	03-008	1963	Female	White	-
	03-009	1984	Female	White	-
	03-010	1980	Female	White	-
	03-011	1968	Female	White	-
	03-012	1975	Female	White	-
	03-013	1952	Female	White	-
	03-014	1972	Female	White	-
	03-015	1966	Female	White	-
	03-016	1969	Female	White	-
	03-017	1977	Female	White	-
	03-018	1971	Female	White	-
	03-019	1949	Female	White	-
	03-020	1968	Female	White	-
	03-021	1964	Female	White	-
	03-022	1959	Female	White	-
	03-023	1959	Female	White	-
	03-024	1970	Female	White	-
	03-025	1969	Female	White	-
	03-026	1943	Female	White	-
	03-027	1973	Female	White	-
	03-028	1974	Female	White	-
	03-029	1961	Female	White	-
	03-030	1974	Male	White	-
	03-031	1971	Female	White	-

- : not applicable

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Listing 4: Subject demographic information

Part 3 of 3

Center	Site ID / Screening No.	Year of birth	Gender	Race	Race other, specify
Mara Graz	03-032	1968	Female	White	-
	03-033	1977	Female	White	-
	03-034	1958	Female	White	-
	03-035	1974	Female	White	-
	03-036	1953	Female	White	-
	03-037	1978	Female	White	-
	03-038	1961	Female	White	-
	03-039	1963	Female	White	-
	03-040	1969	Female	White	-
	03-041	1968	Female	White	-
	03-042	1973	Female	White	-
	03-043	1966	Female	White	-

- : not applicable

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Listing 5: Informed consent

Part 1 of 6

Center	Site ID / Screening No.	Date of informed consent signed	Time of informed consent signed	Check for new/updated consent	Type of new/updated document	Version of new/updated informed consent	Date of new/updated informed consent signed
Dermatology and venerology clinic	01-001	22JAN2019	11:10	-	-	-	-
	01-002	22JAN2019	12:15	-	-	-	-
	01-003	22JAN2019	13:05	-	-	-	-
	01-004	22JAN2019	14:05	-	-	-	-
	01-005	22JAN2019	15:00	-	-	-	-
	01-006	22JAN2019	16:00	-	-	-	-
	01-007	01FEB2019	08:00	-	-	-	-
	01-008	01FEB2019	09:00	Yes	Informed consent to new protocol amendment	2.0; VERSION 10APR2019	27MAY2019
	01-009	01FEB2019	10:00	Yes	Informed consent to new protocol amendment	2.0; VERSION 10APR2019	27MAY2019
	01-010	01FEB2019	11:00	Yes	Informed consent to new protocol amendment	2.0; VERSION 10APR2019	27MAY2019
	01-011	04FEB2019	09:00	-	-	-	-
	01-012	04FEB2019	10:00	-	-	-	-
	01-013	04FEB2019	11:00	-	-	-	-
	01-014	04FEB2019	13:00	-	-	-	-
	01-015	05FEB2019	09:00	-	-	-	-
	01-016	05FEB2019	11:05	-	-	-	-
	01-017	05FEB2019	10:15	Yes	Informed consent to new protocol amendment	2.0; VERSION 10APR2019	27MAY2019
	01-018	05FEB2019	11:05	-	-	-	-
	01-019	05FEB2019	13:05	-	-	-	-

- : not applicable

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Listing 5: Informed consent

Part 2 of 6

Center	Site ID / Screening No.	Date of informed consent signed	Time of informed consent signed	Check for new/updated consent	Type of new/updated document	Version of new/updated informed consent	Date of new/updated informed consent signed
Dermatology and venerology clinic	01-020	05FEB2019	13:05	Yes	Informed consent to new protocol amendment	2.0; VERSION 10APR2019	20MAY2019
	01-021	05FEB2019	13:50	Yes	Informed consent to new protocol amendment	2.0; VERSION 10APR2019	20MAY2019
	01-022	11FEB2019	10:05	-	-	-	-
	01-023	13FEB2019	15:00	-	-	-	-
	01-024	13FEB2019	14:00	-	-	-	-
Yuvell fine aesthetics	01-025	15FEB2019	09:00	-	-	-	-
	02-001	25OCT2018	12:00	-	-	-	-
	02-002	25OCT2018	13:00	-	-	-	-
	02-003	25OCT2018	13:30	-	-	-	-
	02-004	25OCT2018	14:30	-	-	-	-
	02-005	25OCT2018	15:00	-	-	-	-
	02-006	08NOV2018	10:00	-	-	-	-
	02-007	15NOV2018	11:00	-	-	-	-
	02-008	23JAN2019	10:45	-	-	-	-
	02-009	23JAN2019	11:25	-	-	-	-
	02-010	23JAN2019	13:30	-	-	-	-
	02-011	24JAN2019	09:00	-	-	-	-
	02-012	24JAN2019	10:40	-	-	-	-
	02-013	24JAN2019	11:55	-	-	-	-

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Listing 5: Informed consent

Part 3 of 6

Center	Site ID / Screening No.	Date of informed consent signed	Time of informed consent signed	Check for new/updated consent	Type of new/updated document	Version of new/updated informed consent	Date of new/updated informed consent signed
Yuvell fine aesthetics	02-014	24JAN2019	12:50	-	-	-	-
	02-015	24JAN2019	13:40	-	-	-	-
	02-016	24JAN2019	14:45	-	-	-	-
	02-017	24JAN2019	16:00	-	-	-	-
	02-018	29JAN2019	09:00	-	-	-	-
	02-019	29JAN2019	10:00	-	-	-	-
	02-020	29JAN2019	09:40	-	-	-	-
	02-021	30JAN2019	11:15	-	-	-	-
	02-022	30JAN2019	12:05	Yes	Informed consent to new protocol amendment	ADDENDUM V2.0 10APR2019	22MAY2019
	02-023	30JAN2019	13:40	Yes	Informed consent to new protocol amendment	ADDENDUM V2.0 10APR2019	22MAY2019
	02-024	30JAN2019	14:35	-	-	-	-
	02-025	30JAN2019	15:10	Yes	Informed consent to new protocol amendment	ADDENDUM V2.0 10APR2019	23MAY2019
	02-026	31JAN2019	08:45	-	-	-	-
	02-027	31JAN2019	10:55	Yes	Informed consent to new protocol amendment	ADDENDUM V2.0 10APR2019	22MAY2019
	02-028	31JAN2019	11:30	Yes	Informed consent to new protocol amendment	ADDENDUM V2.0 10APR2019	23MAY2019
	02-029	31JAN2019	12:30	-	-	-	-
	02-030	31JAN2019	14:00	-	-	-	-
	02-031	31JAN2019	15:05	-	-	-	-
	02-032	31JAN2019	15:30	-	-	-	-

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Listing 5: Informed consent

Part 4 of 6

Center	Site ID / Screening No.	Date of informed consent signed	Time of informed consent signed	Check for new/updated consent	Type of new/updated document	Version of new/updated informed consent	Date of new/updated informed consent signed
Yuvell fine aesthetics	02-033	31JAN2019	16:25	Yes	Informed consent to new protocol amendment	ADDENDUM V2.0 10APR2019	22MAY2019
Mara Graz	02-034	31JAN2019	17:05	-	-	-	-
	03-001	25NOV2018	13:00	-	-	-	-
	03-002	25NOV2018	17:30	-	-	-	-
	03-003	20JAN2019	14:30	-	-	-	-
	03-004	29NOV2018	15:00	-	-	-	-
	03-005	20JAN2019	12:00	-	-	-	-
	03-006	25NOV2018	19:00	-	-	-	-
	03-007	29NOV2018	16:00	-	-	-	-
	03-008	20JAN2019	16:00	-	-	-	-
	03-009	20JAN2019	12:30	-	-	-	-
	03-010	29NOV2018	11:15	-	-	-	-
	03-011	25NOV2018	14:00	-	-	-	-
	03-012	20JAN2019	11:30	-	-	-	-
	03-013	25NOV2018	11:00	-	-	-	-
	03-014	25NOV2018	18:00	-	-	-	-
	03-015	25NOV2018	12:00	-	-	-	-
	03-016	20JAN2019	09:00	-	-	-	-
	03-017	20JAN2019	15:20	-	-	-	-

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Listing 5: Informed consent

Part 5 of 6

Center	Site ID / Screening No.	Date of informed consent signed	Time of informed consent signed	Check for new/updated consent	Type of new/updated document	Version of new/updated informed consent	Date of new/updated informed consent signed
Mara Graz	03-018	29NOV2018	14:00	-	-	-	-
	03-019	29NOV2018	10:00	-	-	-	-
	03-020	25NOV2018	16:00	-	-	-	-
	03-021	29NOV2018	15:30	-	-	-	-
	03-022	20JAN2019	16:30	-	-	-	-
	03-023	25NOV2018	10:00	-	-	-	-
	03-024	29NOV2018	09:00	-	-	-	-
	03-025	20JAN2019	17:30	-	-	-	-
	03-026	29NOV2018	10:30	-	-	-	-
	03-027	29NOV2018	11:00	-	-	-	-
	03-028	20JAN2019	10:12	-	-	-	-
	03-029	20JAN2019	13:00	-	-	-	-
	03-030	20JAN2019	18:00	-	-	-	-
	03-031	25JAN2019	11:20	-	-	-	-
	03-032	20JAN2019	14:00	-	-	-	-
	03-033	26JAN2019	10:20	-	-	-	-
	03-034	25JAN2019	13:40	-	-	-	-
	03-035	26JAN2019	09:40	-	-	-	-
	03-036	26JAN2019	15:00	-	-	-	-

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Listing 5: Informed consent

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Center	Site ID / Screening No.	Date of informed consent signed	Time of informed consent signed	Check for new/updated consent	Type of new/updated document	Version of new/updated informed consent	Date of new/updated informed consent signed
Mara Graz	03-037	25JAN2019	13:00	-	-	-	-
	03-038	25JAN2019	10:45	-	-	-	-
	03-039	26JAN2019	12:40	-	-	-	-
	03-040	25JAN2019	15:30	-	-	-	-
	03-041	25JAN2019	12:00	-	-	-	-
	03-042	20JAN2019	13:30	-	-	-	-
	03-043	26JAN2019	16:00	-	-	-	-

- : not applicable

Listing 6.1: Visit information (up to Week 16)

Part 1 of 4

Center	Site ID / Screening No.	Day 0	Week 3	Week 6	Week 8	Week 12	Week 16	End of Study
Dermatology and venerology clinic	01-001	22JAN2019	13FEB2019	11MAR2019	03APR2019	30APR2019	24MAY2019	24MAY2019
	01-002	22JAN2019	-	08MAR2019	03APR2019	29APR2019	27MAY2019	27MAY2019
	01-003	22JAN2019	-	15MAR2019	09APR2019	-	-	09APR2019
	01-004	22JAN2019	19FEB2019	05MAR2019	01APR2019	30APR2019	22MAY2019	22MAY2019
	01-005	22JAN2019	15FEB2019	11MAR2019	09APR2019	10MAY2019	27MAY2019	27MAY2019
	01-006	22JAN2019	15FEB2019	11MAR2019	04APR2019	29APR2019	24MAY2019	24MAY2019
	01-007	01FEB2019	21FEB2019	13MAR2019	03APR2019	25APR2019	22MAY2019	22MAY2019
	01-008	01FEB2019	22FEB2019	13MAR2019	03APR2019	28APR2019	27MAY2019	07AUG2019
	01-009	01FEB2019	22FEB2019	13MAR2019	03APR2019	28APR2019	27MAY2019	07AUG2019
	01-010	01FEB2019	22FEB2019	13MAR2019	03APR2019	28APR2019	27MAY2019	22OCT2019
	01-011	04FEB2019	25FEB2019	12MAR2019	08APR2019	29APR2019	23MAY2019	23MAY2019
	01-012	04FEB2019	25FEB2019	12MAR2019	08APR2019	29APR2019	23MAY2019	23MAY2019
	01-013	04FEB2019	25FEB2019	13MAR2019	01APR2019	-	20MAY2019	20MAY2019
	01-014	04FEB2019	25FEB2019	11MAR2019	03APR2019	29APR2019	27MAY2019	27MAY2019
	01-015	05FEB2019	26FEB2019	-	04APR2019	10MAY2019	28MAY2019	28MAY2019
	01-016	05FEB2019	26FEB2019	11MAR2019	03APR2019	30APR2019	27MAY2019	27MAY2019
	01-017	05FEB2019	25FEB2019	14MAR2019	09APR2019	30APR2019	27MAY2019	22JUL2019
	01-018	05FEB2019	26FEB2019	-	07APR2019	30APR2019	27MAY2019	27MAY2019
	01-019	05FEB2019	26FEB2019	12MAR2019	09APR2019	30APR2019	27MAY2019	27MAY2019
	01-020	05FEB2019	26FEB2019	13MAR2019	03APR2019	29APR2019	20MAY2019	04SEP2019
	01-021	05FEB2019	26FEB2019	13MAR2019	03APR2019	29APR2019	20MAY2019	07AUG2019
	01-022	11FEB2019	-	-	-	-	-	05MAR2019
	01-023	13FEB2019	06MAR2019	03APR2019	24APR2019	05JUN2019	12JUN2019	12JUN2019
	01-024	13FEB2019	11MAR2019	03APR2019	28APR2019	29MAY2019	04JUN2019	04JUN2019
	01-025	15FEB2019	11MAR2019	01APR2019	29APR2019	24MAY2019	03JUN2019	03JUN2019
Yuvell fine aesthetics	02-001	25OCT2018	15NOV2018	06DEC2018	20DEC2018	17JAN2019	14FEB2019	14FEB2019

- : not applicable

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Listing 6.1: Visit information (up to Week 16)

Part 2 of 4

Center	Site ID / Screening No.	Day 0	Week 3	Week 6	Week 8	Week 12	Week 16	End of Study
Yuvell fine aesthetics	02-002	25OCT2018	14NOV2018	06DEC2018	19DEC2018	17JAN2019	20FEB2019	20FEB2019
	02-003	25OCT2018	15NOV2018	06DEC2018	20DEC2018	17JAN2019	14FEB2019	14FEB2019
	02-004	25OCT2018	15NOV2018	06DEC2018	20DEC2018	17JAN2019	14FEB2019	14FEB2019
	02-005	25OCT2018	19NOV2018	06DEC2018	20DEC2018	17JAN2019	14FEB2019	14FEB2019
	02-006	08NOV2018	29NOV2018	20DEC2018	09JAN2019	30JAN2019	27FEB2019	27FEB2019
	02-007	15NOV2018	06DEC2018	20DEC2018	10JAN2019	20FEB2019	06MAR2019	06MAR2019
	02-008	23JAN2019	13FEB2019	06MAR2019	20MAR2019	24APR2019	15MAY2019	15MAY2019
	02-009	23JAN2019	13FEB2019	06MAR2019	20MAR2019	17APR2019	15MAY2019	15MAY2019
	02-010	23JAN2019	14FEB2019	07MAR2019	20MAR2019	17APR2019	15MAY2019	15MAY2019
	02-011	24JAN2019	14FEB2019	07MAR2019	21MAR2019	17APR2019	15MAY2019	15MAY2019
	02-012	24JAN2019	13FEB2019	06MAR2019	20MAR2019	17APR2019	15MAY2019	15MAY2019
	02-013	24JAN2019	13FEB2019	06MAR2019	20MAR2019	17APR2019	09MAY2019	09MAY2019
	02-014	24JAN2019	13FEB2019	07MAR2019	21MAR2019	17APR2019	15MAY2019	15MAY2019
	02-015	24JAN2019	21FEB2019	07MAR2019	21MAR2019	17APR2019	15MAY2019	15MAY2019
	02-016	24JAN2019	13FEB2019	07MAR2019	21MAR2019	17APR2019	15MAY2019	15MAY2019
	02-017	24JAN2019	20FEB2019	06MAR2019	21MAR2019	17APR2019	16MAY2019	16MAY2019
	02-018	29JAN2019	21FEB2019	14MAR2019	28MAR2019	17APR2019	16MAY2019	16MAY2019
	02-019	29JAN2019	21FEB2019	14MAR2019	28MAR2019	24APR2019	23MAY2019	23MAY2019
	02-020	29JAN2019	21FEB2019	13MAR2019	27MAR2019	24APR2019	23MAY2019	23MAY2019
	02-021	30JAN2019	21FEB2019	13MAR2019	27MAR2019	24APR2019	23MAY2019	23MAY2019
	02-022	30JAN2019	20FEB2019	13MAR2019	28MAR2019	24APR2019	22MAY2019	02OCT2019
	02-023	30JAN2019	20FEB2019	13MAR2019	27MAR2019	24APR2019	22MAY2019	09OCT2019
	02-024	30JAN2019	21FEB2019	13MAR2019	28MAR2019	25APR2019	23MAY2019	23MAY2019
	02-025	30JAN2019	06MAR2019	14MAR2019	28MAR2019	25APR2019	23MAY2019	02OCT2019
	02-026	31JAN2019	27FEB2019	13MAR2019	28MAR2019	25APR2019	23MAY2019	29MAY2019
	02-027	31JAN2019	21FEB2019	20MAR2019	28MAR2019	24APR2019	22MAY2019	10OCT2019

- : not applicable

Listing 6.1: Visit information (up to Week 16)

Part 3 of 4

Center	Site ID / Screening No.	Day 0	Week 3	Week 6	Week 8	Week 12	Week 16	End of Study
Yuvell fine aesthetics	02-028	31JAN2019	21FEB2019	20MAR2019	27MAR2019	24APR2019	23MAY2019	02OCT2019
	02-029	31JAN2019	21FEB2019	14MAR2019	28MAR2019	25APR2019	23MAY2019	23MAY2019
	02-030	31JAN2019	20FEB2019	20MAR2019	28MAR2019	25APR2019	23MAY2019	23MAY2019
	02-031	31JAN2019	20FEB2019	07MAR2019	27MAR2019	25APR2019	23MAY2019	23MAY2019
Mara Graz	02-032	31JAN2019	21FEB2019	20MAR2019	27MAR2019	24APR2019	22MAY2019	22MAY2019
	02-033	31JAN2019	20FEB2019	13MAR2019	28MAR2019	25APR2019	22MAY2019	09OCT2019
	02-034	31JAN2019	21FEB2019	13MAR2019	28MAR2019	24APR2019	22MAY2019	22MAY2019
	03-001	25NOV2018	16DEC2018	06JAN2019	21JAN2019	17FEB2019	17MAR2019	17MAR2019
	03-002	25NOV2018	16DEC2018	06JAN2019	26JAN2019	17FEB2019	17MAR2019	17MAR2019
	03-003	20JAN2019	10FEB2019	03MAR2019	21MAR2019	14APR2019	05MAY2019	05MAY2019
	03-004	29NOV2018	21DEC2018	08JAN2019	25JAN2019	-	21MAR2019	21MAR2019
	03-005	20JAN2019	10FEB2019	03MAR2019	17MAR2019	14APR2019	05MAY2019	05MAY2019
	03-006	25NOV2018	16DEC2018	06JAN2019	21JAN2019	17FEB2019	16MAR2019	16MAR2019
	03-007	29NOV2018	20DEC2018	08JAN2019	25JAN2019	11FEB2019	20MAR2019	20MAR2019
	03-008	20JAN2019	10FEB2019	03MAR2019	21MAR2019	14APR2019	05MAY2019	05MAY2019
	03-009	20JAN2019	10FEB2019	03MAR2019	21MAR2019	14APR2019	05MAY2019	05MAY2019
	03-010	29NOV2018	20DEC2018	08JAN2019	25JAN2019	11FEB2019	17MAR2019	17MAR2019
	03-011	25NOV2018	16DEC2018	06JAN2019	21JAN2019	17FEB2019	17MAR2019	17MAR2019
	03-012	20JAN2019	10FEB2019	02MAR2019	21MAR2019	14APR2019	05MAY2019	05MAY2019
	03-013	25NOV2018	16DEC2018	06JAN2019	25JAN2019	17FEB2019	17MAR2019	17MAR2019
	03-014	25NOV2018	16DEC2018	06JAN2019	21JAN2019	11FEB2019	17MAR2019	17MAR2019
	03-015	25NOV2018	16DEC2018	06JAN2019	21JAN2019	11FEB2019	16MAR2019	16MAR2019
	03-016	20JAN2019	10FEB2019	03MAR2019	21MAR2019	14APR2019	14MAY2019	14MAY2019
	03-017	20JAN2019	10FEB2019	03MAR2019	21MAR2019	14APR2019	05MAY2019	05MAY2019
	03-018	29NOV2018	21DEC2018	08JAN2019	25JAN2019	11FEB2019	16MAR2019	16MAR2019
	03-019	29NOV2018	20DEC2018	08JAN2019	25JAN2019	10FEB2019	16MAR2019	16MAR2019

- : not applicable

Listing 6.1: Visit information (up to Week 16)

Part 4 of 4

Center	Site ID / Screening No.	Day 0	Week 3	Week 6	Week 8	Week 12	Week 16	End of Study
Mara Graz	03-020	25NOV2018	16DEC2018	06JAN2019	21JAN2019	17FEB2019	17MAR2019	17MAR2019
	03-021	29NOV2018	20DEC2018	08JAN2019	21JAN2019	11FEB2019	16MAR2019	16MAR2019
	03-022	20JAN2019	10FEB2019	03MAR2019	21MAR2019	14APR2019	05MAY2019	05MAY2019
	03-023	25NOV2018	16DEC2018	06JAN2019	21JAN2019	17FEB2019	17MAR2019	17MAR2019
	03-024	29NOV2018	21DEC2018	08JAN2019	25JAN2019	11FEB2019	16MAR2019	16MAR2019
	03-025	20JAN2019	10FEB2019	02MAR2019	21MAR2019	14APR2019	05MAY2019	05MAY2019
	03-026	29NOV2018	20DEC2018	08JAN2019	25JAN2019	11FEB2019	16MAR2019	16MAR2019
	03-027	29NOV2018	21DEC2018	08JAN2019	25JAN2019	11FEB2019	16MAR2019	16MAR2019
	03-028	20JAN2019	10FEB2019	03MAR2019	21MAR2019	14APR2019	05MAY2019	05MAY2019
	03-029	20JAN2019	10FEB2019	03MAR2019	21MAR2019	05MAY2019	14MAY2019	14MAY2019
	03-030	20JAN2019	10FEB2019	03MAR2019	21MAR2019	13APR2019	05MAY2019	05MAY2019
	03-031	25JAN2019	11FEB2019	07MAR2019	21MAR2019	13APR2019	14MAY2019	14MAY2019
	03-032	20JAN2019	10FEB2019	03MAR2019	21MAR2019	14APR2019	05MAY2019	05MAY2019
	03-033	26JAN2019	17FEB2019	02MAR2019	17MAR2019	13APR2019	14MAY2019	14MAY2019
	03-034	25JAN2019	11FEB2019	02MAR2019	17MAR2019	13APR2019	14MAY2019	14MAY2019
	03-035	26JAN2019	17FEB2019	02MAR2019	17MAR2019	13APR2019	14MAY2019	14MAY2019
	03-036	26JAN2019	11FEB2019	02MAR2019	17MAR2019	13APR2019	14MAY2019	14MAY2019
	03-037	25JAN2019	17FEB2019	03MAR2019	17MAR2019	14APR2019	14MAY2019	14MAY2019
	03-038	25JAN2019	11FEB2019	03MAR2019	17MAR2019	14APR2019	14MAY2019	14MAY2019
	03-039	26JAN2019	17FEB2019	02MAR2019	17MAR2019	13APR2019	14MAY2019	14MAY2019
	03-040	25JAN2019	11FEB2019	03MAR2019	17MAR2019	13APR2019	14MAY2019	14MAY2019
	03-041	25JAN2019	10FEB2019	02MAR2019	17MAR2019	13APR2019	14MAY2019	14MAY2019
	03-042	20JAN2019	10FEB2019	03MAR2019	21MAR2019	05MAY2019	14MAY2019	14MAY2019
	03-043	26JAN2019	11FEB2019	03MAR2019	21MAR2019	13APR2019	14MAY2019	14MAY2019

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Listing 6.2: Visit information (follow up phase)

Part 1 of 1

Center	Site ID / Screening No.	Week 16	Week 24	Week 36	End of Study
Dermatology and venerology clinic	01-008	27MAY2019	07AUG2019	-	07AUG2019
	01-009	27MAY2019	07AUG2019	-	07AUG2019
	01-010	27MAY2019	22JUL2019	22OCT2019	22OCT2019
	01-017	27MAY2019	22JUL2019	-	22JUL2019
	01-020	20MAY2019	04SEP2019	-	04SEP2019
Yuvell fine aesthetics	01-021	20MAY2019	07AUG2019	-	07AUG2019
	02-022	22MAY2019	17JUL2019	02OCT2019	02OCT2019
	02-023	22MAY2019	10JUL2019	09OCT2019	09OCT2019
	02-025	23MAY2019	17JUL2019	02OCT2019	02OCT2019
	02-027	22MAY2019	11JUL2019	10OCT2019	10OCT2019
	02-028	23MAY2019	17JUL2019	02OCT2019	02OCT2019
	02-033	22MAY2019	11JUL2019	09OCT2019	09OCT2019

- : not applicable

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Listing 7: Further contacts

Part 1 of 6

Center	Site ID / Screening No.	Has there been any contact by phone, mail or else than visit?	Date of contact	Contact via	Reason for contact	Any relevant information?
Dermatology and venerology clinic	01-001	No	-	-	-	-
	01-002	No	-	-	-	-
	01-003	No	-	-	-	-
	01-004	No	-	-	-	-
	01-005	No	-	-	-	-
	01-006	No	-	-	-	-
	01-007	No	-	-	-	-
	01-008	No	-	-	-	-
	01-009	No	-	-	-	-
	01-010	No	-	-	-	-
	01-011	No	-	-	-	-
	01-012	No	-	-	-	-
	01-013	No	-	-	-	-
	01-014	No	-	-	-	-
	01-015	Yes	06MAR2019	E-Mail	Adverse Event Follow-up	Yes: PATIENT SUFFERS OF ACUTE HERPES LABIALIS AND WILL NOT BE POSSIBLE TO COME FOR SCHEDULED VISIT 3 ON 08.03.2019
	01-016	No	-	-	-	-
	01-017	No	-	-	-	-
	01-018	Yes	12MAR2019	Telephone	Adverse Event Follow-up	No
	01-019	No	-	-	-	-
	01-020	No	-	-	-	-

- : not applicable

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Listing 7: Further contacts

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Center	Site ID / Screening No.	Has there been any contact by phone, mail or else than visit?	Date of contact	Contact via	Reason for contact	Any relevant information?
Dermatology and venerology clinic	01-021	No	-	-	-	-
	01-022	Yes	05MAR2019	Telephone	Other: DROPOUT.	Yes: PATIENT SUFFERS FROM FAMILIAL CATESTROPHES (VATHER DIED AND DAUGHTER SUFFERS FROM BREAST CANCER). PATIENT WANTS TO QUIT THE STUDY.
	01-023	No	-	-	-	-
Yuvell fine aesthetics	01-024	No	-	-	-	-
	01-025	No	-	-	-	-
	02-001	No	-	-	-	-
	02-002	No	-	-	-	-
	02-003	No	-	-	-	-
	02-004	No	-	-	-	-
	02-005	No	-	-	-	-
	02-006	No	-	-	-	-
	02-007	No	-	-	-	-
	02-008	No	-	-	-	-
	02-009	No	-	-	-	-
	02-010	No	-	-	-	-
	02-011	No	-	-	-	-
	02-012	No	-	-	-	-
	02-013	No	-	-	-	-
	02-014	No	-	-	-	-
	02-015	No	-	-	-	-

- : not applicable

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Listing 7: Further contacts

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Center	Site ID / Screening No.	Has there been any contact by phone, mail or else than visit?	Date of contact	Contact via	Reason for contact	Any relevant information?
Yuvell fine aesthetics	02-016	No	-	-	-	-
	02-017	No	-	-	-	-
	02-018	No	-	-	-	-
	02-019	No	-	-	-	-
	02-020	No	-	-	-	-
	02-021	No	-	-	-	-
	02-022	No	-	-	-	-
	02-023	No	-	-	-	-
	02-024	No	-	-	-	-
	02-025	No	-	-	-	-
	02-026	No	-	-	-	-
	02-027	No	-	-	-	-
	02-028	No	-	-	-	-
	02-029	No	-	-	-	-
	02-030	No	-	-	-	-
	02-031	No	-	-	-	-
Mara Graz	02-032	No	-	-	-	-
	02-033	No	-	-	-	-
	02-034	No	-	-	-	-
	03-001	No	-	-	-	-

- : not applicable

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Listing 7: Further contacts

Part 4 of 6

Center	Site ID / Screening No.	Has there been any contact by phone, mail or else than visit?	Date of contact	Contact via	Reason for contact	Any relevant information?
Mara Graz	03-002	No	-	-	-	-
	03-003	No	-	-	-	-
	03-004	No	-	-	-	-
	03-005	No	-	-	-	-
	03-006	No	-	-	-	-
	03-007	No	-	-	-	-
	03-008	No	-	-	-	-
	03-009	No	-	-	-	-
	03-010	No	-	-	-	-
	03-011	No	-	-	-	-
	03-012	No	-	-	-	-
	03-013	No	-	-	-	-
	03-014	No	-	-	-	-
	03-015	No	-	-	-	-
	03-016	No	-	-	-	-
	03-017	No	-	-	-	-
	03-018	No	-	-	-	-
	03-019	No	-	-	-	-
	03-020	No	-	-	-	-
	03-021	No	-	-	-	-

- : not applicable

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Listing 7: Further contacts

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Center	Site ID / Screening No.	Has there been any contact by phone, mail or else than visit?	Date of contact	Contact via	Reason for contact	Any relevant information?
Mara Graz	03-022	No	-	-	-	-
	03-023	No	-	-	-	-
	03-024	No	-	-	-	-
	03-025	No	-	-	-	-
	03-026	No	-	-	-	-
	03-027	No	-	-	-	-
	03-028	No	-	-	-	-
	03-029	No	-	-	-	-
	03-030	No	-	-	-	-
	03-031	No	-	-	-	-
	03-032	No	-	-	-	-
	03-033	No	-	-	-	-
	03-034	No	-	-	-	-
	03-035	No	-	-	-	-
	03-036	No	-	-	-	-
	03-037	No	-	-	-	-
	03-038	No	-	-	-	-
	03-039	No	-	-	-	-
	03-040	No	-	-	-	-
	03-041	No	-	-	-	-

- : not applicable

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Subject eligibility criteria

Inclusion criteria:

- [1] Male or female, 18 years of age or older.
- [2] Subjects deemed by the treating physician to have LCL and/or PR of sufficient baseline severity to merit treatment with Princess® RICH to be corrected.
- [3] A negative urine pregnancy test at Visit 1 and commitment to use an adequate method of birth control for the duration of the clinical investigation (for women of childbearing potential only).
- [4] Healthy skin in the facial area and free of diseases that could interfere in cutaneous aging evaluation.
- [5] Willingness to abstain from any aesthetic or surgical procedures in the treatment area for the duration of the clinical investigation.
- [6] Written signed and dated informed consent.

Exclusion criteria:

- [1] Subjects who tend to develop hypertrophic scars, have pigment disorders or have susceptibility to keloid formation.
- [2] Subjects with a history of autoimmune disease or who are receiving therapy for modification of immune response, e.g. biologics, systemic corticosteroids, cytostatic drugs.
- [3] Subjects who are known to be hypersensitive to hyaluronic acid or glycerol.
- [4] Subjects who have previously received permanent fillers in the areas to be treated.
- [5] Subjects who are pregnant or breast feeding.
- [6] Subjects who are anticoagulated or with history of bleeding disorder.
- [7] Subjects receiving daily treatment with platelet Aggregation inhibitors (e.g. acetylsalicylic acid) unless previously cleared by their primary care physician.
- [8] Subjects who have cutaneous, inflammatory and/or infectious processes (e.g. acne, herpes) present at V0, recurrent herpes simplex or (pre) cancerous lesions in the areas to be treated.
- [9] Subjects with known Diabetes mellitus or uncontrolled systemic diseases in the assessment of the investigator.
- [10] Subjects who have had or are planning to undergo laser therapy, chemical peeling, dermabrasion or botulin toxin treatment in the area to be treated within less than three months prior to and during the course of the study.
- [11] Current participation in another clinical investigation.
- [12] Subjects whose participation in clinical trials is prohibited by the Austrian Medical Devices Act (e.g. persons with a legal custodian appointed due to mental disability, prisoners, soldiers and other members of the armed forces, civil servants).

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Listing 7: Further contacts

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Center	Site ID / Screening No.	Has there been any contact by phone, mail or else than visit?	Date of contact	Contact via	Reason for contact	Any relevant information?
Mara Graz	03-042	No	-	-	-	-
	03-043	No	-	-	-	-

- : not applicable

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Listing 8: Inclusion and exclusion criteria

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				Eligibility criteria not met							
Center	Site ID / Screening No.	Visit	Incl. Cr. 1	Incl. Cr. 2	Incl. Cr. 3	Incl. Cr. 4	Incl. Cr. 5	Incl. Cr. 6	Excl. Cr. 1	Excl. Cr. 2	Excl. Cr. 3
Dermatology and venereology clinic	01-010	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	01-011	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	01-012	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	01-013	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	01-014	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	01-015	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	01-016	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	01-017	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	01-018	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No

				Eligibility criteria not met							
Center	Site ID / Screening No.	Visit	Excl. Cr. 4	Excl. Cr. 5	Excl. Cr. 6	Excl. Cr. 7	Excl. Cr. 8	Excl. Cr. 9	Excl. Cr. 10	Excl. Cr. 11	Excl. Cr. 12
Dermatology and venereology clinic	01-010	Day 0	No	No	No	No	No	No	No	No	No
	01-011	Day 0	No	Not applicable	No	No	No	No	No	No	No
	01-012	Day 0	No	Not applicable	No	No	No	No	No	No	No
	01-013	Day 0	No	Not applicable	No	No	No	No	No	No	No
	01-014	Day 0	No	Not applicable	No	No	No	No	No	No	No
	01-015	Day 0	No	No	No	No	No	No	No	No	No
	01-016	Day 0	No	No	No	No	No	No	No	No	No
	01-017	Day 0	No	Not applicable	No	No	No	No	No	No	No
	01-018	Day 0	No	Not applicable	No	No	No	No	No	No	No

- : not applicable

Listing 8: Inclusion and exclusion criteria

Part 1 of 12

			Eligibility criteria not met								
Center	Site ID / Screening No.	Visit	Incl. Cr. 1	Incl. Cr. 2	Incl. Cr. 3	Incl. Cr. 4	Incl. Cr. 5	Incl. Cr. 6	Excl. Cr. 1	Excl. Cr. 2	Excl. Cr. 3
Dermatology and venereology clinic	01-001	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	01-002	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	01-003	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	01-004	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	01-005	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	01-006	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	01-007	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	01-008	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	01-009	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No

			Eligibility criteria not met								
Center	Site ID / Screening No.	Visit	Excl. Cr. 4	Excl. Cr. 5	Excl. Cr. 6	Excl. Cr. 7	Excl. Cr. 8	Excl. Cr. 9	Excl. Cr. 10	Excl. Cr. 11	Excl. Cr. 12
Dermatology and venereology clinic	01-001	Day 0	No	Not applicable	No	No	No	No	No	No	No
	01-002	Day 0	No	Not applicable	No	No	No	No	No	No	No
	01-003	Day 0	No	Not applicable	No	No	No	No	No	No	No
	01-004	Day 0	No	No	No	No	No	No	No	No	No
	01-005	Day 0	No	Not applicable	No	No	No	No	No	No	No
	01-006	Day 0	No	No	No	No	No	No	No	No	No
	01-007	Day 0	No	No	No	No	No	No	No	No	No
	01-008	Day 0	No	Not applicable	No	No	No	No	No	No	No
	01-009	Day 0	No	Not applicable	No	No	No	No	No	No	No

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Listing 8: Inclusion and exclusion criteria

Part 3 of 12

		Eligibility criteria not met									
Center	Site ID / Screening No.	Visit	Incl. Cr. 1	Incl. Cr. 2	Incl. Cr. 3	Incl. Cr. 4	Incl. Cr. 5	Incl. Cr. 6	Excl. Cr. 1	Excl. Cr. 2	Excl. Cr. 3
Dermatology and venereology clinic	01-019	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	01-020	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	01-021	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	01-022	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	01-023	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
Yuvell fine aesthetics	01-024	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	01-025	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-001	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	02-002	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No

		Eligibility criteria not met									
Center	Site ID / Screening No.	Visit	Excl. Cr. 4	Excl. Cr. 5	Excl. Cr. 6	Excl. Cr. 7	Excl. Cr. 8	Excl. Cr. 9	Excl. Cr. 10	Excl. Cr. 11	Excl. Cr. 12
Dermatology and venereology clinic	01-019	Day 0	No	No	No	No	No	No	No	No	No
	01-020	Day 0	No	Not applicable	No	No	No	No	No	No	No
	01-021	Day 0	No	No	No	No	No	No	No	No	No
	01-022	Day 0	No	Not applicable	No	No	No	No	No	No	No
	01-023	Day 0	No	Not applicable	No	No	No	No	No	No	No
Yuvell fine aesthetics	01-024	Day 0	No	No	No	No	No	No	No	No	No
	01-025	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-001	Day 0	No	No	No	No	No	No	No	No	No
	02-002	Day 0	No	Not applicable	No	No	No	No	No	No	No

- : not applicable

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Listing 8: Inclusion and exclusion criteria

Part 4 of 12

			Eligibility criteria not met								
Center	Site ID / Screening No.	Visit	Incl. Cr. 1	Incl. Cr. 2	Incl. Cr. 3	Incl. Cr. 4	Incl. Cr. 5	Incl. Cr. 6	Excl. Cr. 1	Excl. Cr. 2	Excl. Cr. 3
Yuvell fine aesthetics	02-003	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-004	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-005	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-006	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-007	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-008	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	02-009	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-010	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-011	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No

			Eligibility criteria not met								
Center	Site ID / Screening No.	Visit	Excl. Cr. 4	Excl. Cr. 5	Excl. Cr. 6	Excl. Cr. 7	Excl. Cr. 8	Excl. Cr. 9	Excl. Cr. 10	Excl. Cr. 11	Excl. Cr. 12
Yuvell fine aesthetics	02-003	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-004	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-005	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-006	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-007	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-008	Day 0	No	No	No	No	No	No	No	No	No
	02-009	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-010	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-011	Day 0	No	No	No	No	No	No	No	No	No

- : not applicable

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Listing 8: Inclusion and exclusion criteria

Part 5 of 12

			Eligibility criteria not met								
Center	Site ID / Screening No.	Visit	Incl. Cr. 1	Incl. Cr. 2	Incl. Cr. 3	Incl. Cr. 4	Incl. Cr. 5	Incl. Cr. 6	Excl. Cr. 1	Excl. Cr. 2	Excl. Cr. 3
Yuvell fine aesthetics	02-012	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	02-013	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-014	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-015	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-016	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-017	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-018	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-019	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-020	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No

			Eligibility criteria not met								
Center	Site ID / Screening No.	Visit	Excl. Cr. 4	Excl. Cr. 5	Excl. Cr. 6	Excl. Cr. 7	Excl. Cr. 8	Excl. Cr. 9	Excl. Cr. 10	Excl. Cr. 11	Excl. Cr. 12
Yuvell fine aesthetics	02-012	Day 0	No	No	No	No	No	No	No	No	No
	02-013	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-014	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-015	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-016	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-017	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-018	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-019	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-020	Day 0	No	Not applicable	No	No	No	No	No	No	No

- : not applicable

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Listing 8: Inclusion and exclusion criteria

Part 6 of 12

			Eligibility criteria not met								
Center	Site ID / Screening No.	Visit	Incl. Cr. 1	Incl. Cr. 2	Incl. Cr. 3	Incl. Cr. 4	Incl. Cr. 5	Incl. Cr. 6	Excl. Cr. 1	Excl. Cr. 2	Excl. Cr. 3
Yuvell fine aesthetics	02-021	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-022	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-023	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-024	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-025	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	02-026	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	02-027	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-028	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-029	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No

			Eligibility criteria not met								
Center	Site ID / Screening No.	Visit	Excl. Cr. 4	Excl. Cr. 5	Excl. Cr. 6	Excl. Cr. 7	Excl. Cr. 8	Excl. Cr. 9	Excl. Cr. 10	Excl. Cr. 11	Excl. Cr. 12
Yuvell fine aesthetics	02-021	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-022	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-023	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-024	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-025	Day 0	No	No	No	No	No	No	No	No	No
	02-026	Day 0	No	No	No	No	No	No	No	No	No
	02-027	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-028	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-029	Day 0	No	Not applicable	No	No	No	No	No	No	No

- : not applicable

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Listing 8: Inclusion and exclusion criteria

Part 7 of 12

			Eligibility criteria not met								
Center	Site ID / Screening No.	Visit	Incl. Cr. 1	Incl. Cr. 2	Incl. Cr. 3	Incl. Cr. 4	Incl. Cr. 5	Incl. Cr. 6	Excl. Cr. 1	Excl. Cr. 2	Excl. Cr. 3
Yuvell fine aesthetics	02-030	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	02-031	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	02-032	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	02-033	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
Mara Graz	02-034	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-001	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-002	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-003	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-004	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No

			Eligibility criteria not met								
Center	Site ID / Screening No.	Visit	Excl. Cr. 4	Excl. Cr. 5	Excl. Cr. 6	Excl. Cr. 7	Excl. Cr. 8	Excl. Cr. 9	Excl. Cr. 10	Excl. Cr. 11	Excl. Cr. 12
Yuvell fine aesthetics	02-030	Day 0	No	No	No	No	No	No	No	No	No
	02-031	Day 0	No	No	No	No	No	No	No	No	No
	02-032	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-033	Day 0	No	Not applicable	No	No	No	No	No	No	No
	02-034	Day 0	No	No	No	No	No	No	No	No	No
Mara Graz	03-001	Day 0	No	No	No	No	No	No	No	No	No
	03-002	Day 0	No	No	No	No	No	No	No	No	No
	03-003	Day 0	No	No	No	No	No	No	No	No	No
	03-004	Day 0	No	Not applicable	No	No	No	No	No	No	No

- : not applicable

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Listing 8: Inclusion and exclusion criteria

Part 8 of 12

		Eligibility criteria not met									
Center	Site ID / Screening No.	Visit	Incl. Cr. 1	Incl. Cr. 2	Incl. Cr. 3	Incl. Cr. 4	Incl. Cr. 5	Incl. Cr. 6	Excl. Cr. 1	Excl. Cr. 2	Excl. Cr. 3
Mara Graz	03-005	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-006	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-007	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	03-008	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-009	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-010	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-011	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-012	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-013	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No

		Eligibility criteria not met									
Center	Site ID / Screening No.	Visit	Excl. Cr. 4	Excl. Cr. 5	Excl. Cr. 6	Excl. Cr. 7	Excl. Cr. 8	Excl. Cr. 9	Excl. Cr. 10	Excl. Cr. 11	Excl. Cr. 12
Mara Graz	03-005	Day 0	No	No	No	No	No	No	No	No	No
	03-006	Day 0	No	No	No	No	No	No	No	No	No
	03-007	Day 0	No	Not applicable	No	No	No	No	No	No	No
	03-008	Day 0	No	No	No	No	No	No	No	No	No
	03-009	Day 0	No	No	No	No	No	No	No	No	No
	03-010	Day 0	No	No	No	No	No	No	No	No	No
	03-011	Day 0	No	No	No	No	No	No	No	No	No
	03-012	Day 0	No	No	No	No	No	No	No	No	No
	03-013	Day 0	No	Not applicable	No	No	No	No	No	No	No

- : not applicable

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Listing 8: Inclusion and exclusion criteria

Part 9 of 12

		Eligibility criteria not met									
Center	Site ID / Screening No.	Visit	Incl. Cr. 1	Incl. Cr. 2	Incl. Cr. 3	Incl. Cr. 4	Incl. Cr. 5	Incl. Cr. 6	Excl. Cr. 1	Excl. Cr. 2	Excl. Cr. 3
Mara Graz	03-014	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-015	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-016	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-017	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-018	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-019	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	03-020	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-021	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-022	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No

		Eligibility criteria not met									
Center	Site ID / Screening No.	Visit	Excl. Cr. 4	Excl. Cr. 5	Excl. Cr. 6	Excl. Cr. 7	Excl. Cr. 8	Excl. Cr. 9	Excl. Cr. 10	Excl. Cr. 11	Excl. Cr. 12
Mara Graz	03-014	Day 0	No	No	No	No	No	No	No	No	No
	03-015	Day 0	No	No	No	No	No	No	No	No	No
	03-016	Day 0	No	No	No	No	No	No	No	No	No
	03-017	Day 0	No	No	No	No	No	No	No	No	No
	03-018	Day 0	No	No	No	No	No	No	No	No	No
	03-019	Day 0	No	Not applicable	No	No	No	No	No	No	No
	03-020	Day 0	No	No	No	No	No	No	No	No	No
	03-021	Day 0	No	No	No	No	No	No	No	No	No
	03-022	Day 0	No	No	No	No	No	No	No	No	No

- : not applicable

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Listing 8: Inclusion and exclusion criteria

Part 10 of 12

		Eligibility criteria not met									
Center	Site ID / Screening No.	Visit	Incl. Cr. 1	Incl. Cr. 2	Incl. Cr. 3	Incl. Cr. 4	Incl. Cr. 5	Incl. Cr. 6	Excl. Cr. 1	Excl. Cr. 2	Excl. Cr. 3
Mara Graz	03-023	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	03-024	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-025	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-026	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	03-027	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-028	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-029	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	03-030	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	03-031	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No

		Eligibility criteria not met									
Center	Site ID / Screening No.	Visit	Excl. Cr. 4	Excl. Cr. 5	Excl. Cr. 6	Excl. Cr. 7	Excl. Cr. 8	Excl. Cr. 9	Excl. Cr. 10	Excl. Cr. 11	Excl. Cr. 12
Mara Graz	03-023	Day 0	No	Not applicable	No	No	No	No	No	No	No
	03-024	Day 0	No	No	No	No	No	No	No	No	No
	03-025	Day 0	No	No	No	No	No	No	No	No	No
	03-026	Day 0	No	Not applicable	No	No	No	No	No	No	No
	03-027	Day 0	No	No	No	No	No	No	No	No	No
	03-028	Day 0	No	No	No	No	No	No	No	No	No
	03-029	Day 0	No	Not applicable	No	No	No	No	No	No	No
	03-030	Day 0	No	Not applicable	No	No	No	No	No	No	No
	03-031	Day 0	No	No	No	No	No	No	No	No	No

- : not applicable

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Listing 8: Inclusion and exclusion criteria

Part 11 of 12

			Eligibility criteria not met								
Center	Site ID / Screening No.	Visit	Incl. Cr. 1	Incl. Cr. 2	Incl. Cr. 3	Incl. Cr. 4	Incl. Cr. 5	Incl. Cr. 6	Excl. Cr. 1	Excl. Cr. 2	Excl. Cr. 3
Mara Graz	03-032	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-033	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-034	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-035	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-036	Day 0	Yes	Yes	Not applicable	Yes	Yes	Yes	No	No	No
	03-037	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-038	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-039	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-040	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No

			Eligibility criteria not met								
Center	Site ID / Screening No.	Visit	Excl. Cr. 4	Excl. Cr. 5	Excl. Cr. 6	Excl. Cr. 7	Excl. Cr. 8	Excl. Cr. 9	Excl. Cr. 10	Excl. Cr. 11	Excl. Cr. 12
Mara Graz	03-032	Day 0	No	No	No	No	No	No	No	No	No
	03-033	Day 0	No	No	No	No	No	No	No	No	No
	03-034	Day 0	No	No	No	No	No	No	No	No	No
	03-035	Day 0	No	No	No	No	No	No	No	No	No
	03-036	Day 0	No	Not applicable	No	No	No	No	No	No	No
	03-037	Day 0	No	No	No	No	No	No	No	No	No
	03-038	Day 0	No	No	No	No	No	No	No	No	No
	03-039	Day 0	No	No	No	No	No	No	No	No	No
	03-040	Day 0	No	No	No	No	No	No	No	No	No

- : not applicable

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Listing 8: Inclusion and exclusion criteria

Part 12 of 12

		Eligibility criteria not met									
Center	Site ID / Screening No.	Visit	Incl. Cr. 1	Incl. Cr. 2	Incl. Cr. 3	Incl. Cr. 4	Incl. Cr. 5	Incl. Cr. 6	Excl. Cr. 1	Excl. Cr. 2	Excl. Cr. 3
Mara Graz	03-041	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-042	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No
	03-043	Day 0	Yes	Yes	Yes	Yes	Yes	Yes	No	No	No

		Eligibility criteria not met									
Center	Site ID / Screening No.	Visit	Excl. Cr. 4	Excl. Cr. 5	Excl. Cr. 6	Excl. Cr. 7	Excl. Cr. 8	Excl. Cr. 9	Excl. Cr. 10	Excl. Cr. 11	Excl. Cr. 12
Mara Graz	03-041	Day 0	No	No	No	No	No	No	No	No	No
	03-042	Day 0	No	No	No	No	No	No	No	No	No
	03-043	Day 0	No	No	No	No	No	No	No	No	No

- : not applicable

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Listing 9: Medical / dermatological history

Part 1 of 10

Center	Site ID / Screening No.	Are there any medical history findings for this subject?	MH #	System organ class (SOC)	Preferred term (PT)	Diagnosis / symptom	Start date	Prior to first dosing	Ongoing at end of trial	End date	Any corresponding medication?
Dermatology and venerology clinic	01-001	Yes	01	Musculoskeletal and connective tissue disorders	Rheumatoid arthritis	RHEUMATOID ARTHRITIS	06JUN2016	Yes	Yes	-	Yes
	01-002	Yes	01	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	BREAST CANCER	03SEP2015	Yes	No	12DEC2015	No
	01-003	No	-	-	-	-	-	-	-	-	-
	01-004	No	-	-	-	-	-	-	-	-	-
	01-005	No	-	-	-	-	-	-	-	-	-
	01-006	No	-	-	-	-	-	-	-	-	-
	01-007	Yes	01	Endocrine disorders	Thyroid disorder	THYREOID DYSFUNCTION	11OCT1999	Yes	Yes	-	Yes
		-	02	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Breast cancer	BREAST CANCER	10DEC2014	Yes	No	06JUN2015	Yes
		-	03	Reproductive system and breast disorders	Metrorrhagia	METRRORRHAGY	05OCT2017	Yes	No	05DEC2017	No
	01-008	Yes	01	Vascular disorders	Hypertension	HYPERTENSION	06JUN2013	Yes	Yes	-	Yes
	01-009	Yes	01	Endocrine disorders	Thyroid disorder	THYREOID DYSFUNCTION	10AUG2004	Yes	Yes	-	Yes
	01-010	No	-	-	-	-	-	-	-	-	-

- : not applicable

Listing 9: Medical / dermatological history

Part 2 of 10

Center	Site ID / Screening No.	Are there any medical history findings for this subject?	MH #	System organ class (SOC)	Preferred term (PT)	Diagnosis / symptom	Start date	Prior to first dosing	Ongoing at end of trial	End date	Any corresponding medication?
Dermatology and venerology clinic	01-011	No	-	-	-	-	-	-	-	-	-
	01-012	No	-	-	-	-	-	-	-	-	-
	01-013	Yes	01	Endocrine disorders	Thyroid disorder	THYROID DYSFUNCTION	10FEB2014	Yes	Yes	-	Yes
		-	02	Psychiatric disorders	Depression	DEPRESSION	05JAN2013	Yes	Yes	-	Yes
	01-014	No	-	-	-	-	-	-	-	-	-
	01-015	No	-	-	-	-	-	-	-	-	-
	01-016	No	-	-	-	-	-	-	-	-	-
	01-017	No	-	-	-	-	-	-	-	-	-
	01-018	No	-	-	-	-	-	-	-	-	-
	01-019	No	-	-	-	-	-	-	-	-	-
	01-020	No	-	-	-	-	-	-	-	-	-
	01-021	No	-	-	-	-	-	-	-	-	-

- : not applicable

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Listing 9: Medical / dermatological history

Part 3 of 10

Center	Site ID / Screening No.	Are there any medical history findings for this subject?	MH #	System organ class (SOC)	Preferred term (PT)	Diagnosis / symptom	Start date	Prior to first dosing	Ongoing at end of trial	End date	Any corresponding medication?
Dermatology and venerology clinic	01-022	No	-	-	-	-	-	-	-	-	-
	01-023	No	-	-	-	-	-	-	-	-	-
	01-024	No	-	-	-	-	-	-	-	-	-
	01-025	No	-	-	-	-	-	-	-	-	-
Yuvell fine aesthetics	02-001	No	-	-	-	-	-	-	-	-	-
	02-002	Yes	01	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Benign neoplasm of thyroid gland	BENIGN THYROID TUMOUR	UNUNK2008	Yes	Yes	-	Yes
		-	02	Social circumstances	Menopause	MENOPAUSE	UNUNK2010	Yes	Yes	-	No
	02-003	Yes	01	Social circumstances	Menopause	MENOPAUSE	UNUNK2005	Yes	Yes	-	No
	02-004	Yes	01	Surgical and medical procedures	Thyroidectomy	THYREOIDECTOMY	UNUNK2013	Yes	No	UNUNK2013	Yes
		-	02	Social circumstances	Menopause	MENOPAUSE	UNUNKUNKN	Yes	Yes	-	No
	02-005	Yes	01	Social circumstances	Menopause	MENOPAUSE	UNUNKUNKN	Yes	Yes	-	No
	02-006	Yes	01	Surgical and medical procedures	Female sterilisation	STATUS POST TUBAL LIGATION	UNUNKUNKN	Yes	Yes	-	No

- : not applicable

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Listing 9: Medical / dermatological history

Part 4 of 10

Center	Site ID / Screening No.	Are there any medical history findings for this subject?	MH #	System organ class (SOC)	Preferred term (PT)	Diagnosis / symptom	Start date	Prior to first dosing	Ongoing at end of trial	End date	Any corresponding medication?
Yuvell fine aesthetics	02-007	Yes	01	Social circumstances	Menopause	MENOPAUSE	UNUNKUNKN	Yes	Yes	-	No
	02-008	No	-	-	-	-	-	-	-	-	-
	02-009	Yes	01	Social circumstances	Menopause	MENOPAUSE	UNUNKUNKN	Yes	Yes	-	No
	02-010	Yes	01	Vascular disorders	Hypertension	HYPERTENSION	UNUNK2000	Yes	Yes	-	Yes
		-	02	Vascular disorders	Aortic arteriosclerosis	AORTA CALCIFICATION	UNJAN2017	Yes	Yes	-	Yes
		-	03	Social circumstances	Menopause	MENOPAUSE	UNUNKUNKN	Yes	Yes	-	No
	02-011	No	-	-	-	-	-	-	-	-	-
	02-012	Yes	01	Surgical and medical procedures	Thyroidectomy	THYROID REMOVAL	UNUNK2008	Yes	No	UNUNK2008	Yes
	02-013	Yes	01	Vascular disorders	Hypertension	HYPERTENSION	UNUNK2008	Yes	Yes	-	Yes
		-	02	Surgical and medical procedures	Breast tumour excision	MAMMA CARCINOMA REMOVAL	UNUNK2014	Yes	No	UNUNK2014	Yes
		-	03	Social circumstances	Menopause	MENOPAUSE	UNUNKUNKN	Yes	Yes	-	No
	02-014	Yes	01	Reproductive system and breast disorders	Menopausal symptoms	MENOPAUSAL SYMPTOMS	UNUNK2015	Yes	Yes	-	Yes

- : not applicable

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Listing 9: Medical / dermatological history

Part 5 of 10

Center	Site ID / Screening No.	Are there any medical history findings for this subject?	MH #	System organ class (SOC)	Preferred term (PT)	Diagnosis / symptom	Start date	Prior to first dosing	Ongoing at end of trial	End date	Any corresponding medication?
Yuvell fine aesthetics	02-014	-	02	Social circumstances	Menopause	MENOPAUSE	UNUNKUNKN	Yes	Yes	-	No
	02-015	Yes	01	Social circumstances	Menopause	MENOPAUSE	UNUNKUNKN	Yes	Yes	-	No
	02-016	Yes	01	Social circumstances	Menopause	MENOPAUSE	UNUNKUNKN	Yes	Yes	-	No
	02-017	Yes	01	Social circumstances	Menopause	MENOPAUSE	UNUNKUNKN	Yes	Yes	-	No
	02-018	Yes	01	Social circumstances	Menopause	MENOPAUSE	UNUNKUNKN	Yes	Yes	-	No
	02-019	Yes	01	Surgical and medical procedures	Hysterectomy	HYSTERECTOMY	UNUNK2018	Yes	No	UNUNK2018	No
	02-020	Yes	01	Reproductive system and breast disorders	Menopausal symptoms	MENOPAUSAL SYMPTOMS	UNUNK2016	Yes	Yes	-	Yes
		-	02	Social circumstances	Menopause	MENOPAUSE	UNUNKUNKN	Yes	Yes	-	No
	02-021	Yes	01	Social circumstances	Menopause	MENOPAUSE	UNUNKUNKN	Yes	Yes	-	No
	02-022	Yes	01	Social circumstances	Menopause	MENOPAUSE	UNUNK2014	Yes	Yes	-	No
	02-023	Yes	01	Social circumstances	Menopause	MENOPAUSE	UNUNK2017	Yes	Yes	-	No
	02-024	Yes	01	Endocrine disorders	Hypothyroidism	HYPOTHYROIDISM	UNUNK2016	Yes	Yes	-	Yes

- : not applicable

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Listing 9: Medical / dermatological history

Part 6 of 10

Center	Site ID / Screening No.	Are there any medical history findings for this subject?	MH #	System organ class (SOC)	Preferred term (PT)	Diagnosis / symptom	Start date	Prior to first dosing	Ongoing at end of trial	End date	Any corresponding medication?
Yuvell fine aesthetics	02-024	-	02	Musculoskeletal and connective tissue disorders	Osteoporosis	OSTEOPOROSIS	UNUNK2018	Yes	Yes	-	Yes
		-	03	Social circumstances	Menopause	MENOPAUSE	UNUNKUNKN	Yes	Yes	-	No
	02-025	No	-	-	-	-	-	-	-	-	-
	02-026	Yes	01	Endocrine disorders	Hypothyroidism	HYPOTHYROIDISM	UNUNK2013	Yes	Yes	-	Yes
	02-027	Yes	01	Surgical and medical procedures	Hysterectomy	HYSTERECTOMY	UNUNK2000	Yes	No	UNUNK2000	No
	02-028	Yes	01	Social circumstances	Menopause	MENOPAUSE	UNUNK2007	Yes	Yes	-	No
	02-029	Yes	01	Endocrine disorders	Hypothyroidism	HYPOTHYROIDISM	UNUNK2014	Yes	Yes	-	Yes
		-	02	Vascular disorders	Hypertension	HYPERTENSION	UNUNK2009	Yes	Yes	-	Yes
		-	03	Social circumstances	Menopause	MENOPAUSE	UNUNKUNKN	Yes	Yes	-	No
	02-030	No	-	-	-	-	-	-	-	-	-
	02-031	Yes	01	Endocrine disorders	Hypothyroidism	HYPOTHYROIDISM	UNUNK2005	Yes	Yes	-	Yes
	02-032	Yes	01	Social circumstances	Menopause	MENOPAUSE	UNUNKUNKN	Yes	Yes	-	No

- : not applicable

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Listing 9: Medical / dermatological history

Part 7 of 10

Center	Site ID / Screening No.	Are there any medical history findings for this subject?	MH #	System organ class (SOC)	Preferred term (PT)	Diagnosis / symptom	Start date	Prior to first dosing	Ongoing at end of trial	End date	Any corresponding medication?
Yuvell fine aesthetics	02-033	Yes	01	Surgical and medical procedures	Oophorectomy	OVARIECTOMY	UNUNK2015	Yes	No	UNUNK2015	No
		-	02	Psychiatric disorders	Panic attack	PANIC ATTACKS	UNUNK2016	Yes	Yes	-	Yes
	02-034	Yes	01	Endocrine disorders	Hypothyroidism	HYPOTHYREO SIS	UNUNK2015	Yes	Yes	-	Yes
Mara Graz	03-001	No	-	-	-	-	-	-	-	-	-
	03-002	No	-	-	-	-	-	-	-	-	-
	03-003	No	-	-	-	-	-	-	-	-	-
	03-004	No	-	-	-	-	-	-	-	-	-
	03-005	No	-	-	-	-	-	-	-	-	-
	03-006	No	-	-	-	-	-	-	-	-	-
	03-007	No	-	-	-	-	-	-	-	-	-
	03-008	No	-	-	-	-	-	-	-	-	-
	03-009	No	-	-	-	-	-	-	-	-	-

- : not applicable

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Listing 9: Medical / dermatological history

Part 8 of 10

Center	Site ID / Screening No.	Are there any medical history findings for this subject?	MH #	System organ class (SOC)	Preferred term (PT)	Diagnosis / symptom	Start date	Prior to first dosing	Ongoing at end of trial	End date	Any corresponding medication?
Mara Graz	03-010	No	-	-	-	-	-	-	-	-	-
	03-011	No	-	-	-	-	-	-	-	-	-
	03-012	No	-	-	-	-	-	-	-	-	-
	03-013	No	-	-	-	-	-	-	-	-	-
	03-014	No	-	-	-	-	-	-	-	-	-
	03-015	No	-	-	-	-	-	-	-	-	-
	03-016	No	-	-	-	-	-	-	-	-	-
	03-017	No	-	-	-	-	-	-	-	-	-
	03-018	No	-	-	-	-	-	-	-	-	-
	03-019	No	-	-	-	-	-	-	-	-	-
	03-020	No	-	-	-	-	-	-	-	-	-
	03-021	No	-	-	-	-	-	-	-	-	-

- : not applicable

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Listing 9: Medical / dermatological history

Part 9 of 10

Center	Site ID / Screening No.	Are there any medical history findings for this subject?	MH #	System organ class (SOC)	Preferred term (PT)	Diagnosis / symptom	Start date	Prior to first dosing	Ongoing at end of trial	End date	Any corresponding medication?
Mara Graz	03-022	No	-	-	-	-	-	-	-	-	-
	03-023	No	-	-	-	-	-	-	-	-	-
	03-024	No	-	-	-	-	-	-	-	-	-
	03-025	No	-	-	-	-	-	-	-	-	-
	03-026	No	-	-	-	-	-	-	-	-	-
	03-027	No	-	-	-	-	-	-	-	-	-
	03-028	No	-	-	-	-	-	-	-	-	-
	03-029	No	-	-	-	-	-	-	-	-	-
	03-030	No	-	-	-	-	-	-	-	-	-
	03-031	No	-	-	-	-	-	-	-	-	-
	03-032	No	-	-	-	-	-	-	-	-	-
	03-033	No	-	-	-	-	-	-	-	-	-

- : not applicable

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Listing 9: Medical / dermatological history

Part 10 of 10

Center	Site ID / Screening No.	Are there any medical history findings for this subject?	MH #	System organ class (SOC)	Preferred term (PT)	Diagnosis / symptom	Start date	Prior to first dosing	Ongoing at end of trial	End date	Any corresponding medication?
Mara Graz	03-034	No	-	-	-	-	-	-	-	-	-
	03-035	No	-	-	-	-	-	-	-	-	-
	03-036	No	-	-	-	-	-	-	-	-	-
	03-037	No	-	-	-	-	-	-	-	-	-
	03-038	No	-	-	-	-	-	-	-	-	-
	03-039	No	-	-	-	-	-	-	-	-	-
	03-040	No	-	-	-	-	-	-	-	-	-
	03-041	No	-	-	-	-	-	-	-	-	-
	03-042	No	-	-	-	-	-	-	-	-	-
	03-043	No	-	-	-	-	-	-	-	-	-

- : not applicable

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Listing 10: Urine pregnancy test result

Part 1 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Dermatology and venerology clinic	01-001	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	01-002	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	01-003	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
	01-004	Yes	Day 0	Yes	-	-	-	14:07	Negative
			Week 3	Yes	-	-	-	09:50	Negative
			Week 6	Yes	-	-	-	08:10	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	01-005	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	01-006	Yes	Day 0	Yes	-	-	-	16:10	Negative
			Week 3	Yes	-	-	-	12:55	Negative
			Week 6	Yes	-	-	-	13:20	Negative
			Week 8	Yes	-	-	-	-	Negative

- : not applicable

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Listing 10: Urine pregnancy test result

Part 2 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Dermatology and venerology clinic	01-006	Yes	Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	01-007	Yes	Day 0	Yes	-	-	-	08:05	Negative
			Week 3	Yes	-	-	-	10:30	Negative
			Week 6	Yes	-	-	-	16:55	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	01-008	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
			Week 24	-	-	-	-	-	-
	01-009	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
			Week 24	-	-	-	-	-	-
	01-010	Yes	Day 0	Yes	-	-	-	11:05	Negative
			Week 3	Yes	-	-	-	09:30	Negative
			Week 6	Yes	-	-	-	20:10	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
			Week 24	Yes	-	-	-	-	Negative
			Week 36	Yes	-	-	-	-	Negative

- : not applicable

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Listing 10: Urine pregnancy test result

Part 3 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Dermatology and venerology clinic	01-011	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	01-012	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	01-013	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	01-014	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	01-015	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	01-016	Yes	Day 0	Yes	-	-	-	11:10	Negative
			Week 3	Yes	-	-	-	12:10	Negative

- : not applicable

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Listing 10: Urine pregnancy test result

Part 4 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Dermatology and venerology clinic	01-016	Yes	Week 6	Yes	-	-	-	12:10	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	01-017	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
			Week 24	-	-	-	-	-	-
	01-018	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	01-019	Yes	Day 0	Yes	-	-	-	13:10	Negative
			Week 3	Yes	-	-	-	13:05	Negative
			Week 6	Yes	-	-	-	13:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	01-020	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
			Week 24	-	-	-	-	-	-
	01-021	Yes	Day 0	Yes	-	-	-	14:00	Negative

- : not applicable

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Listing 10: Urine pregnancy test result

Part 5 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Dermatology and venerology clinic	01-021	Yes	Week 3	Yes	-	-	-	15:20	Negative
			Week 6	Yes	-	-	-	15:25	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
			Week 24	Yes	-	-	-	-	Negative
	01-022	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
	01-023	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	01-024	Yes	Day 0	Yes	-	-	-	14:05	Negative
			Week 3	Yes	-	-	-	07:10	Negative
			Week 6	Yes	-	-	-	17:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	01-025	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
Yuvell fine aesthetics	02-001	Yes	Day 0	Yes	-	-	-	12:05	Negative
			Week 3	Yes	-	-	-	17:30	Negative
			Week 6	Yes	-	-	-	17:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative

- : not applicable

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Listing 10: Urine pregnancy test result

Part 7 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Yuvell fine aesthetics	02-006	No (female subject with non-childbearing potential)	Week 16	-	-	-	-	-	-
	02-007	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	02-008	Yes	Day 0	Yes	-	-	-	10:50	Negative
			Week 3	Yes	-	-	-	13:05	Negative
			Week 6	Yes	-	-	-	11:38	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	02-009	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	02-010	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	02-011	Yes	Day 0	Yes	-	-	-	09:03	Negative
			Week 3	Yes	-	-	-	09:07	Negative
			Week 6	Yes	-	-	-	14:55	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative

- : not applicable

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Listing 10: Urine pregnancy test result

Part 6 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Yuvell fine aesthetics	02-001	Yes	Week 16	Yes	-	-	-	-	Negative
	02-002	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	02-003	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	02-004	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	02-005	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	02-006	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-

- : not applicable

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Listing 10: Urine pregnancy test result

Part 8 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Yuvell fine aesthetics	02-011	Yes	Week 16	Yes	-	-	-	-	Negative
	02-012	Yes	Day 0	Yes	-	-	-	10:45	Negative
			Week 3	Yes	-	-	-	11:48	Negative
			Week 6	Yes	-	-	-	12:45	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	02-013	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	02-014	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	02-015	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	02-016	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-

- : not applicable

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Listing 10: Urine pregnancy test result

Part 9 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Yuvell fine aesthetics	02-016	No (female subject with non-childbearing potential)	Week 16	-	-	-	-	-	-
	02-017	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	02-018	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	02-019	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	02-020	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	02-021	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-

- : not applicable

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Listing 10: Urine pregnancy test result

Part 11 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Yuvell fine aesthetics	02-025	Yes	Week 36	Yes	-	-	-	-	Negative
	02-026	Yes	Day 0	Yes	-	-	-	08:50	Negative
			Week 3	Yes	-	-	-	09:00	Negative
			Week 6	Yes	-	-	-	09:15	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	02-027	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
			Week 24	-	-	-	-	-	-
			Week 36	-	-	-	-	-	-
	02-028	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
			Week 24	-	-	-	-	-	-
			Week 36	-	-	-	-	-	-
	02-029	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	02-030	Yes	Day 0	Yes	-	-	-	14:10	Negative

- : not applicable

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Listing 10: Urine pregnancy test result

Part 10 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Yuvell fine aesthetics	02-021	No (female subject with non-childbearing potential)	Week 16	-	-	-	-	-	-
	02-022	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
			Week 24	-	-	-	-	-	-
			Week 36	-	-	-	-	-	-
	02-023	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
			Week 24	-	-	-	-	-	-
			Week 36	-	-	-	-	-	-
	02-024	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	02-025	Yes	Day 0	Yes	-	-	-	15:15	Negative
			Week 3	Yes	-	-	-	15:10	Negative
			Week 6	Yes	-	-	-	13:30	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
			Week 24	Yes	-	-	-	-	Negative

- : not applicable

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Listing 10: Urine pregnancy test result

Part 12 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Yuvell fine aesthetics	02-030	Yes	Week 3	Yes	-	-	-	14:57	Negative
			Week 6	Yes	-	-	-	17:05	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	02-031	Yes	Day 0	Yes	-	-	-	15:10	Negative
			Week 3	Yes	-	-	-	13:50	Negative
			Week 6	Yes	-	-	-	17:38	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	02-032	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	02-033	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
			Week 24	-	-	-	-	-	-
			Week 36	-	-	-	-	-	-
	02-034	Yes	Day 0	Yes	-	-	-	17:10	Negative
			Week 3	Yes	-	-	-	12:10	Negative
			Week 6	Yes	-	-	-	11:15	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative

- : not applicable

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Listing 10: Urine pregnancy test result

Part 13 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Yuvell fine aesthetics	02-034	Yes	Week 16	Yes	-	-	-	-	Negative
Mara Graz	03-001	Yes	Day 0	Yes	-	-	-	13:30	Negative
			Week 3	Yes	-	-	-	16:00	Negative
			Week 6	Yes	-	-	-	15:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-002	Yes	Day 0	Yes	-	-	-	17:30	Negative
			Week 3	Yes	-	-	-	08:00	Negative
			Week 6	Yes	-	-	-	16:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-003	Yes	Day 0	Yes	-	-	-	14:30	Negative
			Week 3	Yes	-	-	-	14:30	Negative
			Week 6	Yes	-	-	-	14:40	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-004	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	03-005	Yes	Day 0	Yes	-	-	-	12:00	Negative
			Week 3	Yes	-	-	-	09:00	Negative
			Week 6	Yes	-	-	-	09:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative

- : not applicable

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Listing 10: Urine pregnancy test result

Part 14 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Mara Graz	03-006	Yes	Day 0	Yes	-	-	-	19:00	Negative
			Week 3	Yes	-	-	-	11:00	Negative
			Week 6	Yes	-	-	-	08:45	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-007	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	03-008	Yes	Day 0	Yes	-	-	-	16:00	Negative
			Week 3	Yes	-	-	-	15:30	Negative
			Week 6	Yes	-	-	-	15:20	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-009	Yes	Day 0	Yes	-	-	-	12:30	Negative
			Week 3	Yes	-	-	-	11:40	Negative
			Week 6	Yes	-	-	-	11:30	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-010	Yes	Day 0	Yes	-	-	-	11:15	Negative
			Week 3	Yes	-	-	-	19:00	Negative
			Week 6	Yes	-	-	-	16:45	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative

- : not applicable

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Listing 10: Urine pregnancy test result

Part 15 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Mara Graz	03-011	Yes	Day 0	Yes	-	-	-	14:00	Negative
			Week 3	Yes	-	-	-	15:40	Negative
			Week 6	Yes	-	-	-	15:30	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-012	Yes	Day 0	Yes	-	-	-	11:30	Negative
			Week 3	Yes	-	-	-	11:00	Negative
			Week 6	Yes	-	-	-	09:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-013	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	03-014	Yes	Day 0	Yes	-	-	-	18:00	Negative
			Week 3	Yes	-	-	-	17:00	Negative
			Week 6	Yes	-	-	-	17:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-015	Yes	Day 0	Yes	-	-	-	12:05	Negative
			Week 3	Yes	-	-	-	12:50	Negative
			Week 6	Yes	-	-	-	12:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative

- : not applicable

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Listing 10: Urine pregnancy test result

Part 16 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Mara Graz	03-016	Yes	Day 0	Yes	-	-	-	09:00	Negative
			Week 3	Yes	-	-	-	08:40	Negative
			Week 6	Yes	-	-	-	11:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-017	Yes	Day 0	Yes	-	-	-	15:20	Negative
			Week 3	Yes	-	-	-	13:30	Negative
			Week 6	Yes	-	-	-	13:30	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-018	Yes	Day 0	Yes	-	-	-	14:00	Negative
			Week 3	Yes	-	-	-	08:00	Negative
			Week 6	Yes	-	-	-	10:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-019	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	03-020	Yes	Day 0	Yes	-	-	-	16:00	Negative
			Week 3	Yes	-	-	-	11:55	Negative
			Week 6	Yes	-	-	-	14:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative

- : not applicable

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Listing 10: Urine pregnancy test result

Part 17 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Mara Graz	03-021	Yes	Day 0	Yes	-	-	-	15:30	Negative
			Week 3	Yes	-	-	-	16:30	Negative
			Week 6	Yes	-	-	-	15:10	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-022	Yes	Day 0	Yes	-	-	-	16:30	Negative
			Week 3	Yes	-	-	-	16:20	Negative
			Week 6	Yes	-	-	-	15:30	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-023	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	03-024	Yes	Day 0	Yes	-	-	-	09:05	Negative
			Week 3	Yes	-	-	-	10:00	Negative
			Week 6	Yes	-	-	-	09:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-025	Yes	Day 0	Yes	-	-	-	17:30	Negative
			Week 3	Yes	-	-	-	17:40	Negative
			Week 6	Yes	-	-	-	11:30	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative

- : not applicable

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Listing 10: Urine pregnancy test result

Part 18 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Mara Graz	03-026	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	03-027	Yes	Day 0	Yes	-	-	-	11:00	Negative
			Week 3	Yes	-	-	-	09:00	Negative
			Week 6	Yes	-	-	-	11:30	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-028	Yes	Day 0	Yes	-	-	-	10:12	Negative
			Week 3	Yes	-	-	-	10:00	Negative
			Week 6	Yes	-	-	-	10:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-029	Yes	Day 0	Yes	-	-	-	13:00	Negative
			Week 3	Yes	-	-	-	17:00	Negative
			Week 6	Yes	-	-	-	16:30	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-030	Not applicable (male subject)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-

- : not applicable

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Listing 10: Urine pregnancy test result

Part 19 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Mara Graz	03-031	Yes	Day 0	Yes	-	-	-	11:22	Negative
			Week 3	Yes	-	-	-	17:00	Negative
			Week 6	Yes	-	-	-	15:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-032	Yes	Day 0	Yes	-	-	-	14:00	Negative
			Week 3	Yes	-	-	-	13:00	Negative
			Week 6	Yes	-	-	-	12:30	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-033	Yes	Day 0	Yes	-	-	-	10:20	Negative
			Week 3	Yes	-	-	-	14:30	Negative
			Week 6	Yes	-	-	-	13:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-034	Yes	Day 0	Yes	-	-	-	13:40	Negative
			Week 3	Yes	-	-	-	13:30	Negative
			Week 6	Yes	-	-	-	12:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-035	Yes	Day 0	Yes	-	-	-	09:42	Negative
			Week 3	Yes	-	-	-	12:10	Negative
			Week 6	Yes	-	-	-	10:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative

- : not applicable

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Listing 10: Urine pregnancy test result

Part 20 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Mara Graz	03-036	No (female subject with non-childbearing potential)	Day 0	-	-	-	-	-	-
			Week 3	-	-	-	-	-	-
			Week 6	-	-	-	-	-	-
			Week 8	-	-	-	-	-	-
			Week 12	-	-	-	-	-	-
			Week 16	-	-	-	-	-	-
	03-037	Yes	Day 0	Yes	-	-	-	13:05	Negative
			Week 3	Yes	-	-	-	15:00	Negative
			Week 6	Yes	-	-	-	14:50	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-038	Yes	Day 0	Yes	-	-	-	10:48	Negative
			Week 3	Yes	-	-	-	08:40	Negative
			Week 6	Yes	-	-	-	17:40	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-039	Yes	Day 0	Yes	-	-	-	12:40	Negative
			Week 3	Yes	-	-	-	16:00	Negative
			Week 6	Yes	-	-	-	14:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-040	Yes	Day 0	Yes	-	-	-	15:30	Negative
			Week 3	Yes	-	-	-	13:00	Negative
			Week 6	Yes	-	-	-	14:10	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative

- : not applicable

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Listing 10: Urine pregnancy test result

Part 21 of 21

Center	Site ID / Screening No.	Is the subject of childbearing potential?	Visit	Urine pregnancy test performed?	Reason not done	Date if unequal to visit date	Date of collection	Time of collection	Result
Mara Graz	03-041	Yes	Day 0	Yes	-	-	-	12:00	Negative
			Week 3	Yes	-	-	-	10:40	Negative
			Week 6	Yes	-	-	-	11:00	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-042	Yes	Day 0	Yes	-	-	-	13:30	Negative
			Week 3	Yes	-	-	-	12:30	Negative
			Week 6	Yes	-	-	-	12:10	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative
	03-043	Yes	Day 0	Yes	-	-	-	16:00	Negative
			Week 3	Yes	-	-	-	11:20	Negative
			Week 6	Yes	-	-	-	10:20	Negative
			Week 8	Yes	-	-	-	-	Negative
			Week 12	Yes	-	-	-	-	Negative
			Week 16	Yes	-	-	-	-	Negative

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 1 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-001	01	ARAVA	Yes	Drug Treatment / Medication	10	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-001	01	Yes	Oral	10JAN2018	Yes	-	Level 4: Selective immunosuppressants Level 3: IMMUNOSUPPRESSANTS Level 2: IMMUNOSUPPRESSANTS Level 1: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-001	01	No	-	Yes	1: RHEUMATOID ARTHRITIS	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 3 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-003	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-003	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-003	-	-	-	-	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 2 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-002	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-002	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-002	-	-	-	-	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 4 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-004	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-004	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-004	-	-	-	-	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 5 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-005	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-005	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-005	-	-	-	-	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 6 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-006	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-006	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-006	-	-	-	-	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 7 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-007	01	EUTHYROX	Yes	Drug Treatment / Medication	88	ug (Microgram, mcg)	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-007	01	Yes	Oral	11OCT1999	Yes	-	Level 4: Thyroid hormones Level 3: THYROID PREPARATIONS Level 2: THYROID THERAPY Level 1: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-007	01	No	-	Yes	1: THYROID DYSFUNCTION	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 9 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-008	01	AMILORIDE HYDROCHLORIDE	Yes	Drug Treatment / Medication	5	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-008	01	Yes	Oral	06JUN2013	Yes	-	Level 4: Other potassium-sparing agents Level 3: POTASSIUM-SPARING AGENTS Level 2: DIURETICS Level 1: CARDIOVASCULAR SYSTEM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-008	01	No	-	Yes	1: HYPERTENSION	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 8 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy Drug Treatment / Medication	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-007	02	TAMOXIFEN	-	Drug Treatment / Medication	10	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-007	02	Yes	Oral	10JUN2015	Yes	-	Level 4: Anti-estrogens Level 3: HORMONE ANTAGONISTS AND RELATED AGENTS Level 2: ENDOCRINE THERAPY Level 1: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-007	02	No	-	Yes	1: BREAST CANCER	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 10 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-009	01	NOVOTHYRAL	Yes	Drug Treatment / Medication	62.5	ug (Microgram, mcg)	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-009	01	Yes	Oral	10AUG2004	Yes	-	Level 4: Thyroid hormones Level 3: THYROID PREPARATIONS Level 2: THYROID THERAPY Level 1: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-009	01	No	-	Yes	1: THYROID DYSFUNCTION	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 11 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-010	01	COPPER IUP	Yes	Non-Drug Therapy	1	Implant	Once	Implant

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-010	01	Yes	Other: INTRAUTERINE	05APR2006	Yes	-	Level 4: Intrauterine contraceptives Level 3: CONTRACEPTIVES FOR TOPICAL USE Level 2: OTHER GYNECOLOGICALS Level 1: GENITO URINARY SYSTEM AND SEX HORMONES

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-010	01	No	-	No	-	-	CONTRACEPTION

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 12 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-011	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-011	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-011	-	-	-	-	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 13 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-012	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-012	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-012	-	-	-	-	-	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 15 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-013	02	TRITTICO	-	Drug Treatment / Medication	25	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-013	02	Yes	Oral	05JAN2013	Yes	-	Level 4: Other antidepressants Level 3: ANTIDEPRESSANTS Level 2: PSYCHOANALEPTICS Level 1: NERVOUS SYSTEM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-013	02	No	-	Yes	1: DEPRESSION	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 14 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-013	01	EUTHYROX	Yes	Drug Treatment / Medication	75	ug (Microgram, mcg)	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-013	01	Yes	Oral	10FEB2014	Yes	-	Level 4: Thyroid hormones Level 3: THYROID PREPARATIONS Level 2: THYROID THERAPY Level 1: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-013	01	No	-	Yes	1: THYROID DYSFUNCTION,	-	-

- : not applicable

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Listing 11: Prior and concomitant therapy

Part 16 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy Drug Treatment / Medication	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-013	03	CITALOPRAM	-	Drug Treatment / Medication	10	mg	Once Daily (QD)	Tablet

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-013	03	Yes	Oral	05JAN2013	Yes	-	Level 4: Selective serotonin reuptake inhibitors Level 3: ANTIDEPRESSANTS Level 2: PSYCHOANALEPTICS Level 1: NERVOUS SYSTEM

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-013	03	No	-	Yes	1: DEPRESSION	-	-

- : not applicable

DOC Code C_CT_CER_005_05	Valid from 09.03.2020	Valid until 08.06.2025	Print date 09.04.2020
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Listing 11: Prior and concomitant therapy

Part 17 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-014	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-014	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-014	-	-	-	-	-	-	-

- : not applicable

DOC Code C_CT_CER_005_05	Valid from 09.03.2020	Valid until 08.06.2025	Print date 09.04.2020
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Listing 11: Prior and concomitant therapy

Part 18 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-015	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-015	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-015	-	-	-	-	-	-	-

- : not applicable

DOC Code C_CT_CER_005_05	Valid from 09.03.2020	Valid until 08.06.2025	Print date 09.04.2020
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Listing 11: Prior and concomitant therapy

Part 19 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-016	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-016	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-016	-	-	-	-	-	-	-

- : not applicable

DOC Code C_CT_CER_005_05	Valid from 09.03.2020	Valid until 08.06.2025	Print date 09.04.2020
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Listing 11: Prior and concomitant therapy

Part 20 of 182

Site ID / Screening No.	CM #	Therapy name	Any medications, therapies or procedures?	Type of therapy	Dose amount/ strength	Dose unit	Dosing frequency per interval	Dosage form
01-017	-	-	No	-	-	-	-	-

Site ID / Screening No.	CM #	Taken/used prior to first dosing?	Route of administration	Start date	Ongoing at end of trial	Stop date	ATC terms
01-017	-	-	-	-	-	-	-

Site ID / Screening No.	CM #	Is this medication used for any AE?	Corresp. adverse event term	Is this therapy used for any medical history?	Corresp. medical history term	Check if this therapy is used for trial indication	Other indication
01-017	-	-	-	-	-	-	-

- : not applicable