

Appendix of Clinical Trial Report 'Ecorhino'

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15 Appendix

15.1 Trial information

15.1.1 Protocol of the clinical trial, patients information and informed consent

The clinical trial was conducted according to the protocol; version 1.1 dated 15th December 2008 including the patient information and informed consent, from the 15th December 2008. No formal protocol amendments were made.

All 3 documents are enclosed separately or filed in the trial master file (TMF) section 2.1.

15.1.2 Sample Case Report Form (CRF) and diary card

A sample CRF is enclosed separately or filed in the TMF section 2.8 with all visit pages including the screening and follow up, with the page for concomitant medication, adverse events, drug accountability and termination page.

A sample diary card is enclosed separately or filed in the TMF section 2.9.

15.1.3 Chairmen and member of the local IEC commission 5

Member			Representative	
Function	Name	Profession	Name	Profession
Facharzt (Chairmen)	Prof. Dr. med. Stefan Müller- Lissner	Facharzt f. Innere Medizin u. Gastro- enterologie/ Leiter einer Klinikabteilung	Prof. Dr. med. Edeltraut Garbe	Fachärztin f. Innere Medizin u. klinische Pharmakologie/ Hochschullehrerin
Facharzt (Stell- vertretender Vorsitzender)	Prof. Dr. med. Michael Dettling	Facharzt f. Psychiatrie u. Neurologie	Prof. Dr. med. Ulrich Keilholz	Facharzt für Innere Medizin, Hämatologie u. Onkologie, OA, Hochschullehrer
Pharmakologe	Prof. Dr. med. Heide Hörtnagl	Fachärztin f. Pharmakologie, Wiss. Mitarbeiterin	Dr. med. Frank Andersohn	Facharzt f. Klinische Pharmakologie/ Wiss. Mitarbeiter
Volljurist	Dr. iur. Marc C. Baumgart	Volljurist/ Rechtsanwalt	Prof. Dr. iur. Dr. phil. Ulrich Lohmann	Volljurist/ Fachhochschullehrer
Biometriker	Dr. med. Peter Schlattmann	Arzt, Biometriker/ Wiss. Mitarbeiter	Dr. rer. nat. Ingeborg Küchler	Mathematikerin/i.R.
Apotheker	Dr. rer. nat. Wolfgang Mehnert	Pharmazeut/ Wiss. Mitarbeiter	Dr. Gertraud Thomas	Pharmazeutin/Leiterin einer Klinikapotheke
Laie/in	Ursula Küchler	Germanistin	Cornelia Biondo	Bürokauffrau/Ver- waltungsangestellte
Laie/in	Dr. phil. Katharina v. Falkenhayn	Philosophin u. Wirtschaftswissen- schaftlerin/ Referentin Dt. Bundestag	Gabriele Lucht	Ev. Theologin/ Landespfarrerin Krankenhausseelsorge
Strahlenschutz	Dr. rer. nat. Lutz Lüdemann	Physiker/Wiss. Mitarbeiter Kinderheilkunde	Dr. med. Thomas Schmitz	Facharzt f. Kinderheil- kunde/ Assistenzarzt, Wiss. Mitarbeiter

15.1.4 List of investigators and other important participants in the clinical trial including curricula vitae

Professor Margitta Worm, MD, is the principle investigator and sponsor of the clinical trial “Ecorhino”. Because, her clinical and experimental investigations focus on the immunomodulation of allergic diseases, she initiated a clinical trial with the *Escherichia coli* Nissle 1917 (EcN). Her clinical priorities are allergies to aeroallergens, autoimmune diseases, food allergy, and environmental medicine. Basic experimental research is focusing on the regulation of IgE synthesis and the immunomodulation of type I allergic diseases.

Curricula vitae Professor Margitta Worm, MD

Date of Birth: 25th October 1964

Present Position: Head of Allergy branch, Clinical study unit; Department of Dermatology and Allergology, Charité – Universitätsmedizin Berlin, Germany

Medical Graduation and/or Other Professional Training:

Sept. 2007 - specialisation course for study coordination in clinical trials; KKS-Charité

Since 2004 - University Professor

2002 - Specialisation in allergy and environmental medicine

2000 - Attendant in dermatology and allergy

1998 - Specialisation in dermatology and venerology

1991 - Medical Doctor

Experience in Controlled Clinical Trials:

Since 1998 principle investigator and investigator in different studies (>40) phases II-III in allergology and dermatology, mainly specific immunotherapy with different allergens, immunomodulation of atopic dermatitis, allergic asthma and autoimmune diseases.

Experienced in audit performance; regular ICH/GCP-training

Claudia Rasche, MD, is sub-investigator in the clinical trial “Ecorhino”. Her clinical interest focuses on atopic dermatitis and type I allergic diseases as well as on autoimmune diseases. She is experienced in conducting clinical trials since 2005.

Curricula vitae Claudia Rasche, MD

Date of Birth: 10th July 1977

Present Position: Assistant Doctor, Department of Dermatology and Allergology, Charité – Universitätsmedizin Berlin, Germany
Currently: off-service since 26th June 2009 due to maternal leave

Medical Graduation and/or Other Professional Training:

Spring 2007 - Specialisation course for clinical trials; KKS-Charité

Autumn 2006 - Basic principles for clinical trials; KKS-Charité including GCP/ICH-training

February 2005 - Resident in dermatology and allergy

December 2004 - Medical Graduation

Experience in Controlled Clinical Trials:

Sub-Investigator in different controlled clinical trials phases II-III since 2005, e.g. specific immunotherapy with different allergens by allergy to aeroallergens and atopic dermatitis, allergic asthma as well as clinical trials with autoimmune diseases. Regular ICH/GCP-training

Guido Heine, MD, is sub-investigator and representative of Claudia Rasche in the clinical trial "Ecorhino". His scientific interest focuses on the immunomodulation of allergic diseases.

Curricula vitae Guido Heine, MD

Date of Birth: 12th May 1975

Present Position: Assistant Doctor, Department of Dermatology and Allergology, Charité – Universitätsmedizin Berlin, Germany

Medical Graduation and/or Other Professional Training:

2009 - Basic principles for clinical trials; KKS-Charité including GCP/ICH-training

2003 - Resident in dermatology and allergy

2002 - Medical Graduation

2000 - doctoral thesis

Experience in Controlled Clinical Trials:

Sub-Investigator in different controlled clinical trials phases II-III since 2002, e.g. specific immunotherapy with different allergens like birch and grass pollen by allergy to aeroallergens and atopic dermatitis, regular ICH/GCP-training

Sabine Dölle studied nutrition science and is specialised in allergology. Her clinical and experimental focuses are atopic dermatitis and type I allergic diseases especially food allergy. She is study coordinator and study assistant in the clinical trial "Ecorhino".

Curricula vitae Sabine Dölle

Date of Birth: 20th October 1980

Present Position: Scientific assistant; Department of Dermatology and Allergology, Charité – Universitätsmedizin Berlin, Germany

Medical Graduation and/or Other Professional Training:

Since 2007 - Study coordinator in IITs

Spring 2006 - Special course for study nurses at clinical Investigation centre; KKS-Charité

January 2006 - Basic principles for clinical trials; KKS-Charité including GCP/ICH-training

Experience in controlled clinical trials:

Study nurse in different controlled clinical trials phases II-III since 2006, e.g. specific immunotherapy with different allergens (house dust mite and birch allergen) by atopic dermatitis; Study coordinator in IITs since 2007; Regular ICH/GCP-training

15.1.5 Sample of labels for the trial medication

Röhrchen Nr. 1

Patienten - Nr.: _____

E. coli Stamm Nissle 1917
(VERUM ODER PLACEBO)

MU 0830 WB

EudraCT-Nr. 2008-006335-12

- Zur klinischen Prüfung bestimmt! -

Inhalt: 60 Kapseln zum Einnehmen

Ch.- B.: 872010

Art der Anwendung:

Von Tag 1 bis Tag 4 je 1 Kapsel, ab Tag 5 je 2 Kapseln täglich zum Frühstück unzerkaut mit ausreichend Flüssigkeit einnehmen.

Bitte im Kühlschrank bei +2 bis + 8°C lagern!
Für Kinder unzugänglich aufbewahren!

verwendbar bis:
ARDEYPHARM GMBH · Herdecke
Tel.: 02330 / 977 677

Röhrchen Nr. 2

Patienten - Nr.: _____

E. coli Stamm Nissle 1917
(VERUM ODER PLACEBO)

MU 0830 WB

EudraCT-Nr. 2008-006335-12

- Zur klinischen Prüfung bestimmt! -

Inhalt: 60 Kapseln zum Einnehmen

Ch.- B.: 872010

Art der Anwendung:

Je 2 Kapseln täglich zum Frühstück unzerkaut mit ausreichend Flüssigkeit einnehmen.

Bitte im Kühlschrank bei +2 bis + 8°C lagern!
Für Kinder unzugänglich aufbewahren!

verwendbar bis:
ARDEYPHARM GMBH · Herdecke
Tel.: 02330 / 977 677

Röhrchen Nr. 3

Patienten - Nr.: _____

E. coli Stamm Nissle 1917
(VERUM ODER PLACEBO)

MU 0830 WB

EudraCT-Nr. 2008-006335-12

- Zur klinischen Prüfung bestimmt! -

Inhalt: 80 Kapseln zum Einnehmen

Ch.- B.: 872010

Art der Anwendung:

Je 2 Kapseln täglich zum Frühstück unzerkaut mit ausreichend Flüssigkeit einnehmen.

Bitte im Kühlschrank bei +2 bis + 8°C lagern!
Für Kinder unzugänglich aufbewahren!

verwendbar bis:
ARDEYPHARM GMBH · Herdecke
Tel.: 02330 / 977 677

Röhrchen Nr. 4

Patienten - Nr.: _____

E. coli Stamm Nissle 1917
(VERUM ODER PLACEBO)

MU 0830 WB

EudraCT-Nr. 2008-006335-12

- Zur klinischen Prüfung bestimmt! -

Inhalt: 60 Kapseln zum Einnehmen

Ch.- B.: 872010

Art der Anwendung:

Je 2 Kapseln täglich zum Frühstück unzerkaut mit ausreichend Flüssigkeit einnehmen.

Bitte im Kühlschrank bei +2 bis + 8°C lagern!
Für Kinder unzugänglich aufbewahren!

verwendbar bis:
ARDEYPHARM GMBH · Herdecke
Tel.: 02330 / 977 677

15.1.6 Randomization scheme and codes (patient identification and treatment assigned)

Block	Random-number*	Assignment (treatment)	–	Screening-number	Comment
1	01	Placebo		S14	
	02	Mutaflor®		S18	
	03	Placebo		S22	
	04	Mutaflor®		S07	
2	05	Mutaflor®		S19	
	06	Placebo		S32	
	07	Mutaflor®		S13	
	08	Placebo		S28	
3	09	Mutaflor®		S01	
	10	Placebo		S30	
	11	Placebo		S03	
	12	Mutaflor®		S21	
4	13	Mutaflor®		S12	
	14	Placebo		S23	
	15	Placebo		S10	
	16	Mutaflor®		S11	
5	17	Placebo		S35	
	18	Placebo		S29	
	19	Mutaflor®		S40	
	20	Mutaflor®		S16	
6	21	Placebo		S33	
	22	Mutaflor®		S39	
	23	Mutaflor®		S20	
	24	Placebo		S31	
7	25	Placebo		S38	
	26	Mutaflor®		S34	
	27	Placebo		S41	
	28	Mutaflor®		S06	
8	29	Mutaflor®		S09	
	30	Mutaflor®		S37	
	31	Placebo		S04	
	32	Placebo		S36	
9	33	Mutaflor®		S44	
	34	Placebo		S46	
	35	Mutaflor®			Not used
	36	Placebo			Not used

* The random-number corresponds to the patient number.

15.1.7 Publications based on the study

A manuscript is in preparation.

15.1.8 Documentation of statistical methods

The statistical analysis plan is enclosed separately or filed in the TMF section 11.2.

15.2 Patients listing

15.2.1 Discontinued patients

Table 15.2.1 Listing of patients who gave informed consent but could not be randomised (screening failure).

S.-No.	P.-No.	Age (years)	Sex	Observation excluded	Date	Reason(s)
S02	No randomisation	19	f	Between screening and visit 1	05-Feb-09	slgE <CAP 2
S05	No randomisation	44	m	Screening	05-Feb-09	Chronic sinusitis
S08	No randomisation	37	m	Between screening and visit 1	24-Feb-09	took antibiotic against gram negative bacteria
S15	No randomisation	47	m	Between screening and visit 1	16-Feb-09	slgE <CAP 2
S17	No randomisation	53	f	Screening	13-Feb-09	Asthma (GINA >I)
S24	No randomisation	28	m	Between screening and visit 1	24-Feb-09	Severe co-disease (spondylarthritis)
S25	No randomisation	28	f	Screening	19-Feb-09	RSS = 09 (<12 points)
S26	No randomisation	32	f	Screening	19-Feb-09	RSS = 10 (<12 points)
S27	No randomisation	23	f	Between screening and visit 1	12-Mar-09	Severe Co-disease (Morphea profunda)
S42	No randomisation	46	m	Screening	03-Mar-09	SPT grass <3 mm
S43	No randomisation	56	f	Between screening and visit 1	10-Mar-09	drew back his consent
S45	No randomisation	20	m	Between screening and visit 1	11-Mar-09	drew back his consent

S.-No. = Screening number, P.-No. = Patient number, f = female m = male

15.2.2 Intend-to-treat and Per-Protocol population

Table 15.2.2 Listing of patients who dropped out after randomisation.

P.-No.	Age (years)	Sex	Date of drop out	Reason(s)
03	36	m	27-Apr-09	Protocol deviation (steroid injection)
11	47	f	28-Aug-09	Did not show up again (moved from Berlin to Hamburg)
30	30	f	27-Mar-09	Adverse event (no. 02)
31	19	m	27-Jul-09	Did not show up again*

*The study team tried several times to approach the patient via e-mail and telephone, unsuccessfully.

Table 15.2.3 Listing of patients who were excluded from the efficacy analysis.

P.-No.	Age (years)	Sex	Date excluded	Reason(s)
01	35	m	24-Nov-09*	Postoperative regular nasal steroid use
03	36	m	27-Apr-09	Drop out
30	30	f	27-Mar-09	Drop out
31	19	m	27-Jul-09	Drop out

*This patient was excluded during the blind data review meeting

15.2.3 Individual primary efficacy criterion

Table 15.2.4 Individual patient data listings of symptom-medication-score

This table is attached separately at the end of the appendix.

15.2.4 Individual secondary efficacy criteria

Table 15.2.5 Individual patient data listings of symptom score

This table is attached separately at the end of the appendix.

Table 15.2.6 Individual patient data listings of medication score

This table is attached separately at the end of the appendix.

Table 15.2.7 Individual patient data listings of skin prick test

Patient-No.	Wheal diameter in mm					
	Screening	Visit 2	Visit 3	Visit 4	Visit 5	Follow-up
1*	7.0	9.0	n.d.	6.5	6.0	6.5
2	9.0	11.5	7.0	7.0	7.5	7.0
3*	6.5	(4.0) n.u.	n.d.	n.d.	6.0	n.d.
4	8.5	6.0	6.5	5.5	4.0	5.0
5	8.5	9.0	9.5	7.5	7.0	7.0
6	10.5	11.0	10.5	9.0	11.5	6.5
7	6.5	8.0	7.5	10.0	10.0	11.0
8	7.0	10.5	5.5	8.5	8.0	6.5
9	7.5	8.5	6.0	5.5	8.0	12.0
10	9.0	5.5	6.0	6.5	6.0	8.5
11	8.5	7.0	5.0	5.5	n.d.	n.d.
12	6.5	5.5	5.0	10.0	6.0	9.0
13	8.5	9.0	10.0	n.d.	7.0	7.0
14	4.5	5.0	3.5	5.5	5.5	7.0
15	8.0	7.0	4.5	6.0	7.5	7.0
16	12.0	13.5	7.0	7.5	14.5	11.5
17	7.0	7.5	6.0	4.0	8.0	8.0
18	8.5	10.5	9.5	8.0	8.0	8.5
19	6.5	6.0	6.0	4.0	6.0	5.0
20	8.5	6.0	5.0	7.0	11.5	9.5
21	5.0	8.0	6.0	9.0	8.5	8.5
22	4.5	0.0	n.d.	5.0	3.0	3.5
23	5.0	6.0	3.0	7.5	3.0	6.5
24	7.5	8.0	7.0	5.0	5.5	5.0
25	12.0	7.0	7.0	8.0	6.5	8.0
26	7.0	(6.0) n.u.	4.0	6.0	7.0	4.0
27	9.0	10.5	n.d.	4.5	8.5	7.0
28	10.5	10.0	7.0	6.5	15.5	9.0
29	6.5	5.5	6.0	12.0	5.0	6.5
30*	4.5	n.d.	n.d.	n.d.	8.0	n.d.
31*	5.0	3.0	4.5	n.d.	n.d.	n.d.
32	12.0	9.5	8.0	7.5	9.5	8.5
33	4.5	6.5	3.0	6.0	5.0	6.0
34	7.0	6.0	5.0	5.0	n.a.	5.5

n.d. = not done, n.u. = not usable due to antihistamine intake; * excluded from PP

Table 15.2.8 Individual patient data listings of the conjunctival provocation test

	conjunctival provocation test (CPT)			
Patient-No.	Visit 1	Dilution (concentration)	Visit 5	Dilution (concentration)
1*	positive	1:5 (20,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
2	positive	1:5 (20,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
3*	positive	1:5 (20,000 SQ/ml)	n.d.	
4	positive	1:1 (100,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
5	positive	1:5 (20,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
6	n.d.		n.d.	
7	n.d.		n.d.	
8	positive	1:5 (20,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
9	positive	1:2 (50,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
10	positive	1:5 (20,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
11	n.d.		n.d.	
12	positive	1:2 (50,000 SQ/ml)	positive	1:1 (100,000 SQ/ml)
13	positive	1:5 (20,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
14	positive	1:2 (50,000 SQ/ml)	positive	1:1 (100,000 SQ/ml)
15	positive	1:1 (100,000 SQ/ml)	positive	1:2 (50,000 SQ/ml)
16	positive	1:5 (20,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
17	positive	1:2 (50,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
18	positive	1:5 (20,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
19	positive	1:5 (20,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
20	n.d.		n.d.	
21	positive	1:5 (20,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
22	negative		n.d.	
23	positive	1:5 (20,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
24	positive	1:5 (20,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
25	positive	1:5 (20,000 SQ/ml)	n.d.	
26	positive	1:5 (20,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
27	positive	1:2 (50,000 SQ/ml)	positive	1:2 (50,000 SQ/ml)
28	positive	1:5 (20,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
29	positive	1:5 (20,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
30*	negative		n.d.	
31*	positive	1:1 (100,000 SQ/ml)		
32	positive	1:5 (20,000 SQ/ml)	positive	1:5 (20,000 SQ/ml)
33	positive	1:2 (50,000 SQ/ml)	n.d.	
34	negative		n.d.	

n.d. = not done; * excluded from PP

Table 15.2.9 Individual patient data listings of specific IgE

	Screening		Visit 5	
Pat-No.	sIgE [kU/l]	CAP	sIgE [kU/l]	CAP
1*	42.30	4	44.00	4
2	19.10	4	14.10	3
3*	22.70	4	n.d.	n.d.
4	9.97	3	11.00	3
5	12.70	3	14.80	3
6	8.99	3	8.73	3

7	92.70	5	65.60	5
8	44.40	4	36.00	4
9	26.00	4	20.20	4
10	36.60	4	37.60	4
11	2.44	2	n.d.	n.d.
12	14.80	3	13.10	3
13	18.70	4	23.30	4
14	15.80	3	20.00	4
15	18.10	4	24.10	4
16	>100	6	>100	6
17	27.60	4	33.80	4
18	17.50	4	17.40	3
19	4.90	3	4.30	3
20	6.04	3	14.20	3
21	11.50	3	10.00	3
22	1.05	2	0.92	2
23	4.14	3	5.66	3
24	11.10	3	10.30	3
25	49.80	4	45.80	4
26	27.00	4	26.80	4
27	31.40	4	30.50	4
28	68.80	5	87.90	5
29	14.40	3	13.10	3
30*	2.63	2	n.d.	n.d.
31*	n.d.	3	n.d.	n.d.
32	>100	6	>100	6
33	1.05	2	2.82	2
34	8.40	3	21.40	4

n.d. = not done; * excluded from PP

Table 15.2.10 Individual patient data listings of life quality assessed by RQLQ

This table is attached separately at the end of the appendix.

Table 15.2.11 Individual patient data listings of symptomfree days

This table is attached separately at the end of the appendix.

Table 15.2.12 Individual patient data listings of global evaluation of rhinoconjunctivitis symptoms

Patient-No	Global evaluation				
	much better	better	same	worse	much worse
1*		x			
2		x			
3*	n.d.	n.d.	n.d.	n.d.	n.d.
4		x			
5		x			
6		x			
7				x	
8			x		
9	x				
10	x				
11	n.d.	n.d.	n.d.	n.d.	n.d.
12			x		
13		x			
14				x	
15		x			
16			x		
17		x			
18		x			
19			x		
20			x		
21				x	
22			x		
23			x		
24		x			
25			x		
26		x			
27	x				
28		x			
29	x				
30*	n.d.	n.d.	n.d.	n.d.	n.d.
31*	n.d.	n.d.	n.d.	n.d.	n.d.
32				x	
33				x	
34				x	

n.d. = not done; * excluded from PP

15.2.5 Individual safety data listings

Table 15.2.13 Individual patient data listing of adverse events

P-No.	AE-No.	Diagnosis	Date of start	Date of end	Intensity	Drug relation	Treatment	Other treatment *	Outcome
1	1	Headache	07-Mar-09	07-Mar-09	mild	n	unchanged	n	recovered
1	2	Headache	02-Mar-09	02-Mar-09	moderate	n	unchanged	y	recovered
1	3	Cold	15-Mar-09	22-Mar-09	moderate	n	unchanged	y	recovered
1	4	Hypertrophy inferior nasal concha	29-Jan-09	29-Apr-09	moderate	n	unchanged	y	recovered
1	5	Sinusitis maxillaris et ethmoidales	29-Jan-09	29-Apr-09	moderate	n	unchanged	y	recovered
1	6	Postoperative pain	29-Apr-09	03-May-09	moderate	n	unchanged	y	recovered
1	7	Postoperative nose breathing issues	29-Apr-09	14-Jun-09	mild	n	unchanged	y	recovered
1	8	Headache	28-May-09	28-May-09	mild	n	unchanged	y	recovered
1	9	Headache	07-Jun-09	08-Jun-09	moderate	n	unchanged	y	recovered
1	10	Headache	09-Jul-09	10-Jul-09	mild	n	unchanged	y	recovered
1	11	Headache	02-Aug-09	02-Aug-09	mild	n	unchanged	y	recovered
2	1	Nausea	02-Mar-09	02-Mar-09	mild	possible	unchanged	n	recovered
2	2	Flatulence (repeated)	04-Mar-09	13-Mar-09	moderate	possible	unchanged	n	recovered
2	3	Abdominal pain (repeated)	04-Mar-09	17-Mar-09	moderate	possible	unchanged	n	recovered
2	4	Abdominal pain	02-Sep-09	06-Sep-09	mild	possible	stopped	n	recovered
2	5	Diarrhoea	02-Sep-09	06-Sep-09	mild	possible	stopped	n	recovered
3	1	Cold	25-Feb-09	02-Mar-09	mild	n	unchanged	y	recovered
3	2	Headache	30-Mar-09	30-Mar-09	moderate	n	unchanged	y	recovered
4	1	Nausea	04-Mar-09	05-Mar-09	mild	possible	unchanged	n	recovered
4	2	Diarrhoea	04-Mar-09	06-Mar-09	mild	possible	unchanged	n	recovered
4	3	Abdominal pain	09-Mar-09	15-Mar-09	mild	possible	unchanged	n	recovered
4	4	Flatulence	23-Mar-09	10-Sep-09	mild	possible	unchanged	n	recovered
4	5	Headache	15-May-09	26-Aug-09	mild	n	unchanged	y	stabilised
5	1	Headache	24-Mar-09	25-Mar-09	moderate	n	unchanged	y	recovered
5	2	Suspicion of abdominal influenza	07-Apr-09	08-Apr-09	mild	n	unchanged	n	recovered

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6	1	Syncope while KPT	02-Mar-09	02-Mar-09	moderate	n	unchanged	n	recovered
6	2	Tooth root inflammation	12-Jun-09	21-Jun-09	moderate	n	unchanged	y	recovered
6	3	Stomach cramp	06-Mar-09	06-Jul-09	moderate	n	unchanged	n	recovered
6	4	Headache	29-Aug-09	29-Aug-09	moderate	n	unchanged	y	recovered
6	5	Sore throat	31-Aug-09	03-Sep-09	mild	n	unchanged	y	recovered
7	1	Diarrhoea	03-Mar-09	08-Mar-09	mild	possible	unchanged	n	recovered
7	2	Strain	17-Aug-09	21-Aug-09	mild	n	unchanged	n	recovered
7	3	Obstipation	02-Sep-09	06-Sep-09	mild	possible	unchanged	n	recovered
8	1	Flatulence	04-Mar-09	06-Mar-09	mild	possible	unchanged	n	recovered
8	2	Diarrhoea	04-Mar-09	06-Mar-09	mild	possible	unchanged	n	recovered
9	1	Acute cervical spinal column syndrome	13-Mar-09	13-Mar-09	moderate	n	unchanged	y	recovered
9	2	Flatulence	06-Mar-09	12-Mar-09	mild	possible	unchanged	n	recovered
9	3	Diarrhoea	06-Mar-09	12-Mar-09	moderate	possible	unchanged	n	recovered
9	4	Cimikosis	12-Apr-09	28-Apr-09	moderate	n	break	y	recovered
9	5	Oral allergy syndrome	10-Jun-09	12-Jun-09	mild	n	unchanged	n	recovered
9	6	Diarrhoea	02-Jul-09	05-Jul-09	mild	n	unchanged	n	recovered
9	7	Abdominal pain	02-Jul-09	05-Jul-09	mild	n	unchanged	n	recovered
9	8	Headache	23-Aug-09	30-Aug-09	mild	n	unchanged	n	recovered
9	9	Cold	30-Aug-09	02-Sep-09	mild	n	unchanged	n	recovered
10	1	Menstrual pain	03-Mar-09	05-Mar-09	mild	n	unchanged	n	recovered
10	2	Headache	06-Mar-09	06-Mar-09	mild	n	unchanged	n	recovered
10	3	Abdominal pain	09-Mar-09	10-Mar-09	mild	possible	unchanged	n	recovered
10	4	Abdominal pain	16-Mar-09	21-Mar-09	moderate	possible	unchanged	n	recovered
10	5	Flatulence	16-Mar-09	21-Mar-09	moderate	possible	unchanged	n	recovered
10	6	Flatulence (repeated)	05-Apr-09	15-Apr-09	mild	possible	unchanged	n	recovered
10	7	Abdominal pain	24-Sep-09	28-Sep-09	mild	possible	unchanged	n	recovered
11	1	Oral allergy syndrome (after apple eating)	03-Mar-09	03-Mar-09	moderate	n	unchanged	n	recovered
11	2	Conjunctivitis (after apple eating)	03-Mar-09	03-Mar-09	moderate	n	unchanged	n	recovered
11	3	Headache	22-Mar-09	22-Mar-09	mild	n	unchanged	n	recovered

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11	4	Respiratory infect	06-May-09	18-May-09	moderate	n	unchanged	y	recovered
11	5	Headache	23-Jul-09	23-Jul-09	moderate	n	unchanged	y	recovered
12	1	Flatulence	23-Mar-09	30-Mar-09	moderate	n	unchanged	n	recovered
12	2	Nausea	23-Mar-09	30-Mar-09	mild	n	unchanged	n	recovered
12	3	Stomach cramp	23-Mar-09	30-Mar-09	moderate	n	unchanged	n	recovered
12	4	Sciatica	04-Mar-09	04-Mar-09	moderate	n	unchanged	y	recovered
12	5	Headache	23-Mar-09	25-Mar-09	mild	n	unchanged	n	recovered
12	6	Headache	30-Mar-09	30-Mar-09	moderate	n	unchanged	y	recovered
12	7	Cold	15-May-09	17-May-09	moderate	n	unchanged	y	recovered
12	8	Headache	09-May-09	09-May-09	mild	n	unchanged	y	recovered
12	9	Headache	22-May-09	22-May-09	mild	n	unchanged	n	recovered
12	10	Eye infection	16-Jun-09	21-Jun-09	moderate	n	unchanged	y	recovered
13	1	Headache	07-Mar-09	07-Mar-09	moderate	n	unchanged	y	recovered
13	2	Pain (elbow joint)	26-Jun-09	n.k.	moderate	n	unchanged	y	ongoing
14	1	Tension headache	09-Mar-09	09-Mar-09	mild	n	unchanged	n	recovered
14	2	Cold	17-Mar-09	25-Mar-09	mild	n	unchanged	n	recovered
14	3	Cold	23-Jun-09	26-Jun-09	mild	n	unchanged	y	recovered
14	4	Headache	06-Jul-09	09-Jul-09	mild	n	unchanged	n	recovered
14	5	Flatulence	13-Jul-09	13-Aug-09	mild	n	unchanged	n	recovered
14	6	Diarrhoea	13-Jul-09	13-Aug-09	mild	n	unchanged	n	recovered
14	7	Pain (ankle after insect bite)	19-Aug-09	19-Aug-09	mild	n	unchanged	y	recovered
15	1	Flatulence	06-Mar-09	12-Mar-09	mild	possible	unchanged	n	recovered
15	2	Diarrhoea	06-Mar-09	12-Mar-09	mild	possible	unchanged	n	recovered
15	3	Insulin resistance	30-Apr-09	n.k.	moderate	n	unchanged	y	ongoing
15	4	Hyperuricemia	30-Apr-09	n.k.	mild	n	unchanged	n	ongoing
15	5	Headache	11-May-09	16-May-09	mild	n	unchanged	y	recovered
15	6	Cold	25-Sep-09	02-Oct-09	mild	n	unchanged	n	recovered
16	None								
17	1	Headache	10-Mar-09	12-Mar-09	moderate	n	unchanged	y	recovered

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17	2	Suspicion of abdominal influenza	12-Mar-09	12-Mar-09	mild	n	unchanged	n	recovered
17	3	Headache	21-Mar-09	21-Mar-09	mild	n	unchanged	n	recovered
17	4	Pharyngitis	30-Aug-09	06-Sep-09	mild	n	unchanged	y	recovered
18	1	Eczema	10-Mar-09	14-Mar-09	moderate	n	unchanged	n	recovered
18	2	Angina	18-Apr-09	28-Apr-09	moderate	n	unchanged	y	recovered
18	3	Hypermenorrhoe	23-Apr-09	n.k.	mild	n	unchanged	y	ongoing
18	4	Headache	06-Jun-09	06-Jun-09	moderate	n	unchanged	y	recovered
18	5	Headache (repeated)	05-Aug-09	30-Aug-09	moderate	n	unchanged	y	recovered
18	6	Eczema	03-Aug-09	11-Aug-09	mild	n	unchanged	n	recovered
19	1	Oral allergy syndrome after nut eating	13-Mar-09	13-Mar-09	moderate	n	unchanged	n	recovered
19	2	Dyspnoea	09-Mar-09	n.k.	moderate	n	unchanged	y	stabilised
19	3	Sore throat	10-Mar-09	12-Mar-09	moderate	n	unchanged	y	recovered
19	4	Cold	18-May-09	20-May-09	mild	n	unchanged	y	recovered
20	1	Cold	16-Mar-09	22-Mar-09	moderate	n	unchanged	y	recovered
20	2	Allergic rhinoconjunctivitis	13-Apr-09	20-May-09	moderate	n	unchanged	y	recovered
21	1	Stomach cramp	09-Mar-09	09-Mar-09	mild	possible	unchanged	n	recovered
21	2	Diarrhoea	09-Mar-09	09-Mar-09	mild	possible	unchanged	n	recovered
21	3	Abdominal cramping	28-Mar-09	28-Mar-09	mild	n	unchanged	n	recovered
21	4	Headache	30-Mar-09	31-Mar-09	mild	n	unchanged	n	recovered
21	5	Abdominal cramping	14-Apr-09	14-Apr-09	mild	n	unchanged	n	recovered
21	6	Headache	20-Apr-09	20-Apr-09	mild	n	unchanged	n	recovered
21	7	Tooth fistula	05-May-09	n.k.	mild	n	unchanged	y	stabilised
22	1	Allergic rhinoconjunctivitis	06-Mar-09	20-May-09	moderate	n	unchanged	y	recovered
22	2	Flatulence (repeated)	21-Mar-09	31-Mar-09	moderate	n	unchanged	n	recovered
22	3	Cold	08-Apr-09	13-Apr-09	moderate	n	unchanged	y	recovered
22	4	Acroathritis (arm)	03-Jul-09	10-Jul-09	mild	n	unchanged	y	recovered
23	1	Sinusitis	08-Mar-09	12-Mar-09	moderate	n	unchanged	y	recovered
23	2	Cold	12-May-09	14-May-09	moderate	n	unchanged	y	recovered
23	3	Cold	17-Jul-09	20-Jul-09	moderate	n	unchanged	y	recovered

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23	4	Wisdom tooth inflammation	17-Aug-09	28-Aug-09	moderate	n	unchanged	y	recovered
24	1	Allergic rhinoconjunctivitis	20-Mar-09	20-May-09	moderate	n	unchanged	y	recovered
24	2	Sinusitis / flu	05-May-09	22-May-09	moderate	n	unchanged	y	recovered
24	3	Abdominal influenza	08-Aug-09	13-Aug-09	moderate	n	unchanged	y	recovered
24	4	Flu	17-Aug-09	20-Aug-09	moderate	n	unchanged	y	recovered
25	1	Diarrhoea (repeated)	27-Apr-09	30-Apr-09	mild	n	unchanged	n	recovered
25	2	Pain (knee joint)	06-Aug-09	n.k.	moderate	n	unchanged	y	ongoing
26	1	Nausea	12-Mar-09	14-Mar-09	mild	possible	unchanged	n	recovered
26	2	Abdominal pain	12-Mar-09	14-Mar-09	mild	possible	unchanged	n	recovered
26	3	Allergic rhinoconjunctivitis	11-Mar-09	20-May-09	moderate	n	unchanged	y	recovered
26	4	Infection of the higher respiratory	14-Mar-09	20-Mar-09	moderate	n	unchanged	y	recovered
26	5	Headache	12-Mar-09	12-Mar-09	mild	n	unchanged	n	recovered
26	6	Headache	15-Mar-09	15-Mar-09	mild	n	unchanged	n	recovered
26	7	Diarrhoea	17-Mar-09	17-Mar-09	mild	n	unchanged	n	recovered
26	8	Flatulence (repeated)	06-Apr-09	07-Jun-09	mild	n	unchanged	n	recovered
26	9	Stiff neck	30-Jul-09	31-Aug-09	mild	n	unchanged	y	recovered
27	1	Allergic rhinoconjunctivitis	04-Mar-09	20-May-09	mild	n	unchanged	y	recovered
27	2	Sore throat	17-Apr-09	18-Apr-09	mild	n	unchanged	n	recovered
28	1	Cold	27-Feb-09	05-Mar-09	moderate	n	unchanged	y	recovered
28	2	Headache	28-Mar-09	28-Mar-09	mild	n	unchanged	y	recovered
28	3	Headache	19-Jun-09	19-Jun-09	moderate	n	unchanged	y	recovered
28	4	Cold	13-Jul-09	17-Jul-09	mild	n	unchanged	y	recovered
29	1	Stiff neck, tensioned neck	10-Mar-09	10-Mar-09	moderate	n	unchanged	y	recovered
29	2	Headache	24-Mar-09	25-Mar-09	moderate	n	unchanged	y	recovered
29	3	Sore throat	04-Jun-09	05-Jun-09	mild	n	unchanged	y	recovered
29	4	Pharyngitis	03-Aug-09	14-Aug-09	mild	n	unchanged	y	recovered
30	1	Cold	02-Mar-09	09-Mar-09	moderate	n	unchanged	y	recovered
30	2	Flatulence	12-Mar-09	22-Mar-09	severe	sure	stopped	n	recovered
31	1	Cold	28-Feb-09	08-Mar-09	mild	n	unchanged	y	recovered

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31	2	Cold	19-Mar-09	26-Mar-09	mild	n	unchanged	n	recovered
31	3	Cold	n.k.-n.k.-09	n.k.-n.k.-09	mild	n	unchanged	n	n.k.
32	1	Cold	02-Mar-09	10-Mar-09	moderate	n	unchanged	y	recovered
32	2	Abdominal pain	17-Mar-09	17-Mar-09	mild	possible	unchanged	n	recovered
32	3	Headache	18-Mar-09	18-Mar-09	mild	n	unchanged	n	recovered
32	4	Abdominal pain	21-Mar-09	21-Mar-09	mild	possible	unchanged	n	recovered
32	5	Headache	21-Mar-09	21-Mar-09	mild	n	unchanged	n	recovered
32	6	Abdominal pain	25-Mar-09	25-Mar-09	mild	possible	unchanged	n	recovered
32	7	Cold	26-May-09	02-Jun-09	mild	n	unchanged	n	recovered
32	8	Cold	27-Sep-09	06-Oct-09	mild	n	unchanged	n	recovered
33	1	Cold	30-Mar-09	01-Apr-09	mild	n	unchanged	y	recovered
33	2	Flatulence	12-Mar-09	18-Mar-09	mild	possible	unchanged	n	recovered
34	1	Allergic rhinoconjunctivitis	07-Apr-09	20-May-09	moderate	n	unchanged	y	recovered
34	2	Headache	26-Apr-09	26-Apr-09	mild	n	unchanged	y	recovered
34	3	Dry eyes	22-Mar-09	n.k.	mild	n	unchanged	y	stabilised
34	4	Headache	01-May-09	06-May-09	mild	n	unchanged	y	recovered
34	5	Abdominal pain	02-May-09	06-May-09	mild	n	unchanged	n	recovered
34	6	Headache	24-May-09	24-May-09	mild	n	unchanged	n	recovered
34	7	Headache	28-May-09	06-Jun-09	moderate	n	unchanged	y	recovered
34	8	Infection of the upper respiratory tract	16-Jun-09	29-Jun-09	moderate	n	unchanged	y	recovered
34	9	Headache	10-Aug-09	10-Aug-09	mild	n	unchanged	y	recovered
34	10	Eye infection	14-Aug-09	23-Aug-09	mild	n	unchanged	y	recovered

*Co-medication is listed in [Table 15.2.14](#); abbreviations: n.k. – not known, n – no, y - yes

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Table 15.2.14 Individual patient date listing concomitant medication

P-No.	Name of medication	Strength	Route	Frequency	Date of start	Date of end	Ongoing	Disease
1	ASS	500mg	oral	1x1/d	02-Mar-09	02-Mar-09	n	Headache
1	Aspirin	500mg	oral	PRN	15-Mar-09	22-Mar-09	n	Cold
1	nose drops	n.k.	nasal	PRN	15-Mar-09	22-Mar-09	n	Cold
1	Cetirizin	10mg	oral	PRN	21-Apr-09	20-May-09	n	allergic rhinoconjunctivitis
1	Propafenon	150mg	i.v.	n.k.	29-Apr-09	29-Apr-09	n	Nose operation
1	Sulfentanil	20µg	i.v.	n.k.	29-Apr-09	29-Apr-09	n	Nose operation
1	Esmeron	35mg	i.v.	n.k.	29-Apr-09	29-Apr-09	n	Nose operation
1	Ultiva	1mg	i.v.	0.1-0.05-0.1 ug/ml/h	29-Apr-09	29-Apr-09	n	Nose operation
1	Propofol	20mg/ml	i.v.	35 ml/kg/h	29-Apr-09	29-Apr-09	n	Nose operation
1	Pefalgan	2.5g	i.v.	n.k.	29-Apr-09	29-Apr-09	n	Nose operation
1	Dexamethason	4mg	i.v.	n.k.	29-Apr-09	29-Apr-09	n	Nose operation
1	Atropin	0.5mg	i.v.	n.k.	29-Apr-09	29-Apr-09	n	Nose operation
1	Dormicum	7.5mg	oral	n.k.	29-Apr-09	29-Apr-09	n	Premedication nose operation
1	Cefuroxim	500mg	oral	2x1/d	29-Apr-09	06-May-09	n	Sinusitis maxillaris et ethmoidales
1	Ibuprofen	400mg	oral	PRN	29-Apr-09	03-May-09	n	Perioperative pain of the nose
1	Nasonex	50µg/puff	nasal	2x/d	05-May-09	07-Jun-09	n	Postoperative nose breathing issues
1	Nasonex	50µg/puff	nasal	1x/d	08-Jun-09	14-Jun-09	n	Postoperative nose breathing issues
1	Ibuprofen	200mg	oral	1-3x/d	28-May-09	28-May-09	n	Headache
1	Ibuprofen	200mg	oral	1-3x/d	07-Jun-09	07-Jun-09	n	Headache
1	Ibuprofen	400mg	oral	1x/d	09-Jul-09	10-Jul-09	n	Headache
1	Ibuprofen	300mg	oral	1x/d	02-Aug-09	02-Aug-09	n	Headache
2	Leios	n.a.	oral	1x1/d	27-Jun-05		y	Contraception
3	Paracetamol	500mg	oral	3x1/d	25-Feb-09	27-Feb-09	n	Cold
3	Aerius	5mg	oral	PRN	02-Mar-09	n.k.	n	allergic rhinoconjunctivitis
3	Vividrin akut Augentropfen (eye drops)	0.015mg	conjunctival	2x/d	02-Mar-09	n.k.	n	allergic rhinoconjunctivitis
3	Vividrin akut Nasenspray (nasal spray)	0.14mg	nasal	3x/d	02-Mar-09	n.k.	n	allergic rhinoconjunctivitis
3	Volon A Injection	80mg	i.m.	1x1/d	09-Apr-09	09-Apr-09	n	severe allergic rhinoconjunctivitis issues
4	Ramipril	5mg	oral	1x1/d	30-Jun-05		y	Hypertension
4	HCT	12.5mg	oral	1x1/d	30-Jun-05		y	Hypertension

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4	Nora Step	n.a.	oral	1x1/d	n.k. n.k. 97		y	Contraception
4	Dolormin extra	400mg	oral	1x1/d	15-May-09	26-Aug-09	n	Headache
4	Paracetamol	500mg	oral	1x1/d	15-May-09	26-Aug-09	n	Headache
4	Otrivin Nasentropfen (nasal drops)	0.1%	nasal	PRN	28-Jun-09	26-Aug-09	n	allergic rhinoconjunctivitis
5	Humalog	100/E/ml	subcutaneous	24.4 IE	18-Jun-05		y	Diabetes 1
5	Humalog	100/E/ml	subcutaneous	PRN	18-Jun-05		y	Diabetes 1
5	Paracetamol	500mg	oral	2x1/d	24-Mar-09	25-Mar-09	n	Headache
6	Clindamycin	300mg	oral	3-6x/d	16-Jun-09	25-Jun-09	n	Tooth root inflammation
6	Diclofenac	400mg	oral	1-2x/d	15-Jun-09	21-Jun-09	n	Tooth root inflammation
6	Dormicum	2.5mg	i.v.	1x1/d	06-Jul-09	06-Jul-09	n	Gastroscopy
6	Aspirin	500mg	oral	1x1/d	29-Aug-09	29-Aug-09	n	Headache
6	Hexural Gurgellösung (gargling solution)	n.a.	oral	1x/d	01-Sep-09	03-Sep-09	n	Sore throat
7	None							
8	Aarane N	n.a.	inhalative	PRN	n.k.-n.k.-02		y	Asthma
9	L-Thyroxin	75µg	oral	1x1/d	27-Jun-05		y	Hypothyroidism
9	ASS	500mg	oral	2x1/d	13-Mar-09	13-Mar-09	n	Acute cervical spinal column syndrome
9	Ecural	1mg	cutaneous	PRN	21-Apr-09	25-Apr-09	n	Eczema (Cimikosis)
9	Aerius	5mg	oral	PRN	21-Apr-09	28-Apr-09	n	Eczema (Cimikosis)
10	Mirena	52mg	intrauterine	14µg/d	24-Jun-05		y	Contraception
11	Voltaren dispers	50mg	oral	PRN	30-Jun-05		y	backache, <i>status post</i> prolapse
11	Ibuprofen	600mg	oral	PRN	01-Jul-05		y	backache, <i>status post</i> prolapse
11	Cetirizin	10mg	oral	PRN	10-Apr-09	19-Apr-09	n	allergic rhinoconjunctivitis
11	Cromo-Augentropfen (eye drops)	20mg/1ml	conjunctival	1x/d	04-Apr-09	06-Apr-09	n	allergic rhinoconjunctivitis
11	Livocab-Augentropfen (eye drops)	0.5mg/1ml	conjunctival	PRN	14-Apr-09	28-Apr-09	n	allergic rhinoconjunctivitis
11	Nasonex	50µg/puff	nasal	PRN	10-Apr-09	26-Apr-09	n	allergic rhinoconjunctivitis
11	Ibuprofen	400mg	oral	1x1/d	06-May-09	06-May-09	n	Respiratory infect
11	Codeintropfen	1mg/drop	oral	n.k.	11-May-09	14-May-09	n	Respiratory infect
11	Neoangin Lutschtablette (lozenge)	n.a.	oral	PRN	11-May-09	18-May-09	n	Respiratory infect
11	Dolormin	400mg	oral	1x1/d	23-Jul-09	23-Jul-09	n	Headache
12	Omeprazol	20mg	oral	1x1/d	06-Jan-09	15-Feb-09	n	Cholecystectomy
12	L-Thyroxin	125µg	oral	1x1/d	26-Jun-05		y	Hypothyroidism

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12	Ibuprofen	400mg	oral	1x1/d	04-Mar-09	04-Mar-09	n	lumba spine syndrom
12	Ibuprofen	400mg	oral	PRN	n.k.-n.k.-06		y	Pain, <i>status post</i> prolapse
12	Cellufresh	10ml	conjunctival	PRN	01-Jan-06		y	Dry eyes
12	Calcium D3 Lutschtablette (lozenge)	n.a.	oral	1x1/d	n.k.-Jan-09	09-Apr-09	n	Osteoporosis prophylaxis
12	Paracetamol	500mg	oral	1x1/d	30-Mar-09	30-Mar-09	n	Headache
12	Ibuprofen	400mg	oral	3x1/d	21-Feb-09	23-Feb-09	n	Bone build-up treatment
12	Ibuprofen	400mg	oral	2x1/d	24-Feb-09	24-Feb-09	n	Bone build-up treatment
12	Allergodil Augentropfen (eye drops)	0.5mg/ml	conjunctival	PRN	06-Apr-09	26-Apr-09	n	Allergic rhinoconjunctivitis
12	Vividrin Nasenspray (nasal spray)	20mg/ml	nasal	PRN	06-Apr-09	26-Apr-09	n	Allergic rhinoconjunctivitis
12	Lorano	10mg	oral	1x1/d	06-Apr-09	26-Apr-09	n	Allergic rhinoconjunctivitis
12	Neoangin	n.a.	oral	PRN	15-May-09	17-May-09	n	Cold
12	Ibuprofen	400mg	oral	1x1/d	09-May-09	09-May-09	n	Headache
12	Refobacim Augentropfen (eye drops)	n.k.	conjunctival	2x/d	19-Jun-09	21-Jun-09	n	Eye infection
13	Sumatriptane	50mg	oral	PRN	n.k.-n.k.-05		y	Migraine
13	Diovan	82mg	oral	1x1/d	n.k.-n.k.-07		y	Hypertension
13	Rabeprazol	20mg	oral	1x1/d	09-Feb-09	10-Mar-09	n	Dysphagia
13	Tramadol	100mg/1ml	oral	PRN	n.k.-n.k.-05		y	Prolapse
13	ASS	500mg	oral	PRN	07-Mar-09	07-Mar-09	n	Headache
13	Diclac	75mg	oral	2x1/d	26-Jun-09		y	Pain (elbow joint)
14	Minisiston	n.a.	oral	1x1/d	19-Jun-05		y	Contraception
14	Advantan	1mg	topic	PRN	n.k. 2007		y	Atopic dermatitis
14	Aerodur	0.5mg/puff	inhalative	PRN	n.k. 1994		y	Asthma
14	Cetirizin	10mg	oral	1x1/d	23-Apr-09	20-May-09	n	Allergic rhinoconjunctivitis
14	Otrivin Nasenspray (nasal spray)	1mg	nasal	PRN	22-Apr-09	20-May-09	n	Allergic rhinoconjunctivitis
14	Grippostat	n.a.	oral	1x1/d	23-Jun-09	26-Jun-09	n	Cold
14	Otrivin Nasenspray (nasal spray)	n.k.	nasal	1x/d	23-Jun-09	26-Jun-09	n	Cold
14	Bronchicum Elixir	n.a.	oral	PRN	23-Jun-09	26-Jun-09	n	Cold
14	Reactine Duo	n.a.	oral	PRN	23-Jul-09	n.k.	n.k.	Allergic rhinoconjunctivitis
14	Loratadin	10mg	oral	PRN	23-Jul-09	n.k.	n.k.	Allergic rhinoconjunctivitis
14	Ibuprofen	400mg	oral	1x1/d	19-Aug-09	19-Aug-09	n	Pain (foot)

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15	Orfiril	650mg	oral	2x1/d	21-Jun-05		y	Epilepsy
15	Nora Step	n.a.	oral	1x1/d	22-Jun-05		y	Contraception
15	Cetirizin	10mg	oral	PRN	09-Mar-09	20-May-09	n	Allergic rhinitis
15	Metformin	500mg	oral	1x1/d	15-May-09	21-May-09	n	Insulin resistance
15	Metformin	1000mg	oral	1x1/d	22-May-09	28-May-09	n	Insulin resistance
15	Metformin	1500mg	oral	1x1/d	29-May-09		y	Insulin resistance
15	Sinupret forte	n.a.	oral	2x1/d	14-May-09	15-May-09	n	Headache
15	Sinupret forte	n.a.	oral	1x1/d	16-May-09	16-May-09	n	Headache
16	None							
17	Ibuprofen	400mg	oral	1x1/d	10-Mar-09	10-Mar-09	n	Headache
17	Paracetamol	500mg	oral	1x1/d	12-Mar-09	12-Mar-09	n	Headache
17	DHU "Heuschnupfenmittel"	n.a.	oral	PRN	03-Apr-09	30-Apr-09	n	Allergic rhinoconjunctivitis
17	Loratadin	10mg	oral	1x1/d	09-Apr-09	29-Apr-09	n	Allergic rhinoconjunctivitis
17	Meditonsin Tropfen (oral drops)	n.a.	oral	PRN	30-Aug-09	06-Sep-09	n	Pharyngitis
17	Paracetamol	500mg	oral	1-2x/d	30-Aug-09	06-Sep-09	n	Pharyngitis
18	Ibuprofen	400mg	oral	PRN	17-Jun-05		y	Headache
18	Penicillin	1.5 M	oral	3x/d	20-Apr-09	30-Apr-09	n	Angina
18	Ferro Sanol® (iron additives)	100mg	oral	1x1/d	24-Apr-09		y	Hypermenorrhea
18	Unofem	1.5mg	oral	1x1/d	24-Jul-09	24-Jul-09	n	Contraception <i>post coitum</i>
18	Ibuprofen	400mg	oral	PRN	06-Jun-09	06-Jun-09	n	Headache
18	Ibuprofen	400mg	oral	PRN	05-Aug-09	30-Aug-09	n	Headache
19	Dolormin Migräne	400mg	oral	PRN	21-Jun-05		y	Migraine
19	Xysal	5mg	oral	1x1/d	19-Mar-09		y	Dyspnoea
19	Salbutamol	0.12mg	inhalative	PRN	23-Mar-09		y	Dyspnoea
19	Calcium	800mg	oral	1x1/d	n.k.		y	Osteoporosis prophylaxis
19	Paracetamol	500mg	oral	1x1/d	10-Mar-09	12-Mar-09	n	Sore throat
19	Prospan "Hustenliquid"	n.a.	oral	PRN	10-Mar-09	12-Mar-09	n	Sore throat
19	Exen	n.a.	oral	PRN	18-May-09	28-May-09	n	Cold
20	Grippostad C	n.a.	oral	3x2/d	16-Mar-09	22-Mar-09	n	Cold
20	Cetirizin	10mg	oral	PRN	13-Apr-09	22-Apr-09	n	Allergic rhinoconjunctivitis
21	Tuberculinum bovinum	D200	oral	1x/d	07-May-09	07-May-09	n	Tooth fistula
21	Heparsulfat	D30	oral	2x/d	09-May-09		y	Tooth fistula
21	Berberin	D3	oral	3x/d	09-May-09		y	Tooth fistula

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22	Bisoprolol	5mg	oral	0.5/d	28-Jun-05		y	Sinustachycardy
22	Thyronajod	25µg	oral	1x1/d	29-Jun-05		y	Struma
22	Paracetamol	500mg	oral	PRN	n.k.-n.k.-95		y	Headache
22	Ibuprofen	400mg	oral	PRN	n.k.-n.k.-95		y	Headache
22	Cetirizin	10mg	oral	PRN	06-Mar-09	27-Apr-09	n	Allergic rhinoconjunctivitis
22	Nasonex	50µg/puff	nasal	PRN	06-Mar-09	27-Apr-09	n	Allergic rhinoconjunctivitis
22	Paracetamol	500mg	oral	3x1/d	08-Apr-09	12-Apr-09	n	Cold
22	Paracetamol	500mg	oral	1x1/d	13-Apr-09	13-Apr-09	n	Cold
22	Ibuprofen	400mg	oral	1x1/d	03-Jul-09	03-Jul-09	n	Pain (elbow joint)
23	Paracetamol	500mg	oral	PRN	29-Jun-05		y	Headache
23	Valette	n.a.	oral	1x1/d	25-Jun-05		y	Contraception
23	Gelomyrtol forte	n.a.	oral	3x1/d	08-Mar-09	12-Mar-09	n	Sinusitis
23	Ibuprofen	400mg	oral	PRN	08-Mar-09	12-Mar-09	n	Sinusitis
23	Aspirin plus C	n.a.	oral	PRN	n.k.	n.k.	n.k.	Headache
23	Neoangin Lutschtablette (lozenge)	n.a.	oral	PRN	12-May-09	14-May-09	n	Cold
23	Aspirin plus C	n.a.	oral	2x1/d	12-May-09	14-May-09	n	Cold
23	Aspirin plus C	n.a.	oral	1-2x/d	17-Jul-09	20-Jul-09	n	Cold
23	Doxycyclin	200mg	oral	1x1/d	18-Aug-09	27-Aug-09	n	Wisdom tooth inflammation
23	Ibuprofen	400mg	oral	PRN	18-Aug-09	21-Aug-09		Wisdom tooth inflammation
24	Thyronajod	50µg	oral	1x1/d	25-Jun-05		y	Struma
24	Valette	n.a.	oral	1x1/d	28-Jun-05		y	Contraception
24	Allergodil Nasenspray (nasal spray)	0.14mg/puff	nasal	1x/d	20-Mar-09	04-May-09	n	Allergic rhinoconjunctivitis
24	Amoxicillin	500mg	oral	2x1/d	11-May-09	22-May-09	n	Sinusitis
24	Antinal	n.k.	oral	3x1/d	08-Aug-09	13-Aug-09	n	Abdominal influenza
24	Buscopan	10mg	oral	3x/d	08-Aug-09	13-Aug-09	n	Abdominal influenza
24	Kapect Compound	n.k.	oral	3x/d	08-Aug-09	13-Aug-09	n	Abdominal influenza
24	Actifed	n.k.	oral	3x/d	17-Aug-09	20-Aug-09	n	Flu
24	Pradoral	n.k.	oral	3-5x/d	17-Aug-09	20-Aug-09	n	Flu
25	Voltaren Resinat Kapseln (capsule)	75mg	oral	1-2x/d	06-Aug-09	11-Aug-09	n	Pain (knee joint)
26	Triamcinolon 0.1; Triclosum 1.0	n.a.	topic	PRN	25-Jun-05		y	Atopic dermatitis
26	Cetirizin	10mg	oral	PRN	11-Mar-09	29-Apr-09	n	Allergic rhinoconjunctivitis
26	Nasic Nasenspray (nasal spray)	10mg	nasal	PRN	14-Mar-09	29-Apr-09	n	Cold / Allergic rhinoconjunctivitis

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26	Weleda Heuschnupfenspray (nasal spray)	n.a.	nasal	PRN	04-Apr-09	29-Apr-09	n	Allergic rhinitis
26	Ibuprofen	400mg	oral	1x1	11-Aug-09	15-Aug-09	n	stiff neck
27	Nebilet	5mg	oral	1x1/d	28-Jun-05		y	Hypertension
27	Zamipress	10/20mg	oral	1x1/d	28-Jun-05		y	Hypertension
27	Allopurinol	300mg	oral	1x1/d	23-Jun-05		y	Hyperurecemia
27	Cetirizin	10mg	oral	PRN	18-Mar-09	03-May-09	n	Allergic rhinoconjunctivitis
27	Rupafin	10mg	oral	PRN	19-Apr-09	27-Apr-09	n	Allergic rhinoconjunctivitis
28	Paracetamol	500mg	oral	1x1/d	01-Mar-09	01-Mar-09	n	Cold
28	Paracetamol	1000mg	oral	1x1/d	02-Mar-09	02-Mar-09	n	Cold
28	Yasmin	n.a.	oral	1x1/d	01-Nov-08		y	Contraception
28	Paracetamol	500mg	oral	1x1/d	28-Mar-09	28-Mar-09	n	Headache
28	Paracetamol	500mg	oral	1x1/d	19-Jun-09	19-Jun-09	n	Headache
28	Paracetamol	500mg	oral	1x1/d	13-Jul-09	17-Jul-09	n	Headache
29	L-Thyroxin	75µg	oral	1x1/d	30-Jun-05		y	Hypothyroidism
29	Aspirin	500mg	oral	1x1/d	24-Mar-09	25-Mar-09	n	Headache
29	Mega Penicillin	1M	oral	1x1/d	05-Aug-09	14-Aug-09	n	Pharyngitis
30	Paracetamol	500mg	oral	PRN	03-Mar-09	05-Mar-09	n	Cold
31	Nasenspray E ratio (nasal spray)	n.k.	nasal	PRN	02-Mar-09	05-Mar-09	n	Cold
32	L-Thyroxin	75µg	oral	0.5/d	n.k.-Dec-08		y	Hypothyroidism
32	Codeinum phosphoricum	30mg	oral	3x/d	02-Mar-09	08-Mar-09	n	Cold
33	ASS	500mg	oral	PRN	20-Jun-05		y	Headache
33	Asperin plus C	n.a.	oral	1x1/d	31-Mar-09	31-Mar-09	n	Cold
34	Hyaluronsäure Augentropfen (eye drops)	n.k.	conjunctival	PRN	22-Mar-09	15-Apr-09	n	Dry eyes
34	Cromo Hexal	20mg/1ml	conjunctival	PRN	07-Apr-09	27-Apr-09	n	allergic rhinoconjunctivitis
34	Salbutamol	0.12mg/puff	inhalative	PRN	20-Apr-09	23-Apr-09	n	allergic rhinoconjunctivitis
34	Aerius	5mg	oral	1x1/d	22-Apr-09	23-Apr-09	n	allergic rhinoconjunctivitis
34	Paracetamol	500mg	oral	2x1/d	26-Apr-09	26-Apr-09	n	Headache
34	Sinupret	n.a.	oral	PRN	01-May-09	05-May-09	n	Headache
34	Ibuprofen	400mg	oral	1x1/d	05-May-09	05-May-09	n	Headache
34	Ibuprofen	400mg	oral	1x1/d	30-May-09	30-May-09	n	Headache
34	Ibuprofen	400mg	oral	1x1/d	06-Jun-09	06-Jun-09	n	Headache
34	Ibuprofen	600mg	oral	1x1/d	16-Jun-09	29-Jun-09	n	Headache

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34	Nasenspray Ratiopharm (nasal spray)	7ml/puff	nasal	PRN	16-Jun-09	29-Jun-09	n	Infection of the upper respiratory tract
34	Bronchipret Tabletten (pills)	n.a.	oral	PRN	16-Jun-09	29-Jun-09	n	Infection of the upper respiratory tract
34	Sinupret	n.a.	oral	PRN	16-Jun-09	29-Jun-09	n	Infection of the upper respiratory tract
34	Paracetamol	500mg	oral	PRN	16-Jun-09	29-Jun-09	n	Infection of the upper respiratory tract
34	Ibuprofen	600mg	oral	1x1/d	10-Aug-09	10-Aug-09	n	Headache
34	herbal eye drops	n.k.	conjunctival	PRN	14-Aug-09	14-Aug-09	n	Eye infection
34	ASS	500mg	oral	1x1/d	14-Aug-09	14-Aug-09	n	Eye infection
34	Paracetamol	500mg	oral	2x1/d	15-Aug-09	15-Aug-09	n	Eye infection

Abbreviations: PRN – pro re nata (as needed), i.v. – intravenous, i.m. – intramuscular, n.a. – not applicable, n.k. – not known, n - no, y - yes

Table 15.2.15 Individual patient date listing of laboratory values (ITT)

Patient-No	safety laboratory						full blood count										automatic (diff BB)				
	Sodium (mmol/l)	Potassium (mmol/l)	Creatinine (mg/ dl)	ALT (U/l)	AP (U/l)	GGT (U/l)	Leucocytes/nl	Erythrocytes/pl	Haemoglobin (g/dl)	Haematocrit (l/l)	MCH (pg)	MCHC (g/dl)	MCV (fl)	RDW (%)	Thrombocytes nl	MPV (V)	Neutrophiles/nl	Lymphocytes/nl	Monocytes/nl	Eosinophiles/nl	Basophiles/nl
1	142	4.1	n.d.	21.0	58.0	12.0	4.8	4.7	14.8	0.4	31.3	33.9	92.0	12.3	192.0	12.0	2.8	1.3	0.3	0.3	0.1
2	138	4.5	0.8	16.0	44.0	13.0	5.4	5.0	13.4	0.4	26.9	32.4	83.0	13.5	341.0	9.0	3.3	1.4	0.5	0.1	0.0
3	139	4.1	1.1	37.0	50.0	39.0	6.3	5.0	15.8	0.5	31.7	35.2	90.0	12.2	195.0	12.0	3.7	2.1	0.4	0.1	0.0
4	142	4.0	0.8	20.0	35.0	18.0	6.6	4.5	12.9	0.4	28.5	33.3	86.0	12.9	249.0	12.0	3.4	2.4	0.6	0.1	0.0
5	139	3.7	0.9	41.0	100.0	74.0	7.6	5.1	15.5	0.5	30.2	34.1	88.0	12.1	233.0	9.0	3.7	3.1	0.7	0.1	0.0
6	140	4.3	0.8	27.0	74.0	16.0	7.0	4.7	14.2	0.4	30.1	34.6	87.0	12.8	201.0	11.0	3.7	2.5	0.7	0.1	0.0
7	139	4.1	1.0	25.0	62.0	16.0	5.6	5.5	16.4	0.5	30.1	36.4	83.0	13.4	199.0	11.0	2.2	2.9	0.4	0.1	0.0
8	141	4.2	0.9	64.0	53.0	43.0	5.2	5.2	15.2	0.4	29.3	35.5	82.0	12.6	224.0	10.0	2.6	1.9	0.6	0.1	0.0
9	142	4.6	0.7	20.0	44.0	18.0	4.7	4.2	12.5	0.4	30.1	34.2	88.0	13.0	333.0	11.0	2.0	2.1	0.4	0.2	0.1
10	140	4.0	0.7	16.0	38.0	14.0	8.1	4.5	13.5	0.4	29.9	33.9	88.0	12.2	252.0	10.0	62.0	29.0	7.0	n.d.	n.d.
11	139	4.0	0.8	13.0	42.0	10.0	6.5	4.2	12.2	0.4	29.1	32.5	90.0	12.5	220.0	10.0	4.4	1.6	0.4	0.1	0.0
12	138	4.3	0.8	18.0	45.0	16.0	5.3	4.0	11.8	0.4	29.5	33.1	89.0	14.1	247.0	12.0	2.7	1.9	0.5	0.2	0.0
13	139	4.0	n.d.	32.0	58.0	24.0	7.5	5.2	14.9	0.5	28.4	33.2	86.0	13.2	298.0	11.0	4.7	2.2	0.5	0.1	0.0
14	136	4.0	0.9	14.0	67.0	15.0	9.3	4.5	12.8	0.4	28.8	33.6	86.0	12.7	237.0	11.0	6.5	1.5	0.6	0.6	0.0

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15	137	4.6	n.d.	9.0	64.0	17.0	6.4	4.5	13.5	0.4	29.9	32.8	91.0	13.3	290.0	10.0	2.7	3.1	0.6	0.0	0.0
16	137	3.3	1.0	16.0	79.0	16.0	5.6	5.3	14.4	0.4	27.3	33.8	81.0	12.7	258.0	10.0	3.3	1.5	0.8	0.1	0.0
17	141	4.2	0.7	33.0	56.0	28.0	5.2	5.2	15.5	0.4	29.9	35.4	85.0	12.6	250.0	9.0	2.3	2.2	0.5	0.1	0.1
18	138	4.3	0.8	16.0	21.0	13.0	6.2	4.8	13.1	0.4	27.2	32.7	83.0	13.5	253.0	10.0	3.7	1.9	0.4	0.3	0.0
19	141	4.2	0.7	16.0	62.0	12.0	5.0	4.6	14.0	0.4	30.4	34.1	89.0	13.3	188.0	11.0	2.9	1.7	0.4	0.1	0.0
20	141	3.8	0.9	36.0	100.0	19.0	4.9	4.9	14.4	0.4	29.7	33.8	88.0	12.8	276.0	10.0	2.8	1.5	0.4	0.1	0.0
21	138	4.4	0.7	15.0	51.0	10.0	4.8	4.2	12.8	0.4	30.4	33.4	91.0	12.8	231.0	11.0	2.1	2.2	0.4	0.1	0.0
22	138	4.5	0.8	15.0	70.0	13.0	6.0	4.3	13.9	0.4	32.6	33.3	98.0	11.9	313.0	10.0	3.5	1.8	0.4	0.3	0.1
23	137	4.0	0.8	36.0	59.0	28.0	7.4	4.4	12.8	0.4	28.8	32.4	89.0	13.3	234.0	11.0	3.9	2.5	0.6	0.5	0.0
24	138	4.4	0.7	12.0	50.0	9.0	6.1	4.4	12.6	0.4	28.9	32.0	90.0	12.4	270.0	10.0	3.4	2.1	0.5	0.1	0.0
25	141	3.9	1.1	58.0	58.0	35.0	6.2	5.3	15.6	0.5	29.2	33.3	88.0	12.5	298.0	11.0	4.3	1.3	0.4	0.0	0.0
26	142	4.1	0.8	17.0	42.0	13.0	6.6	4.4	14.2	0.4	32.0	34.5	93.0	12.8	264.0	11.0	3.6	2.1	0.7	0.2	0.0
27	137	4.0	1.0	40.0	61.0	85.0	8.2	4.9	14.5	0.4	29.8	34.0	88.0	12.6	230.0	11.0	4.5	2.9	0.6	0.1	0.1
28	137	3.6	0.9	24.0	43.0	11.0	7.1	4.4	12.6	0.4	28.8	33.1	87.0	11.6	237.0	10.0	3.3	3.2	0.4	0.2	0.1
29	138	4.2	0.7	29.0	62.0	17.0	6.0	5.0	14.3	0.4	28.8	33.5	86.0	13.3	179.0	13.0	3.9	1.6	0.3	0.1	0.0
30	141	4.0	0.9	23.0	47.0	9.0	6.1	4.2	12.7	0.4	30.0	32.3	93.0	12.9	232.0	11.0	3.8	1.6	0.5	0.1	0.1
31	139	3.9	0.7	14.0	74.0	15.0	6.6	4.9	14.3	0.4	29.4	34.4	85.0	12.6	212.0	10.0	3.5	2.2	0.4	0.4	0.1
32	140	3.6	1.1	20.0	66.0	16.0	5.0	5.0	13.5	0.4	26.9	33.0	82.0	12.9	276.0	10.0	2.3	1.8	0.8	0.1	0.0
33	143	3.4	0.6	25.0	75.0	20.0	7.3	4.7	12.6	0.4	26.9	32.2	83.0	14.3	353.0	11.0	3.0	3.4	0.7	0.2	0.1
34	141	3.5	0.6	15.0	72.0	18.0	8.0	4.6	13.6	0.4	29.6	33.7	88.0	12.6	321.0	10.0	4.9	2.0	0.6	0.5	0.0

below normal range; above normal range; all deviations were minor and not clinical relevant

Table 15.2.16 Individual patient date listing of vital signs (ITT)

S- No.	P- No.	Screening			Visit 5		
		Pulse Beat	Blood pressure Systolic	Blood pressure Diastolic	Puls e Beat	Blood pressure Systolic	Blood pressure Diastolic
14	1	53	130	90	56	125	65
18	2	80	110	70	80	120	60
22	3	100	130	85	80	130	90
7	4	60	130	90	68	110	60
19	5	73	130	80	80	125	75
32	6	60	130	90	64	110	70
13	7	80	130	90	80	129	70
28	8	60	110	80	58	110	60
1	9	80	115	80	72	110	60
30	10	72	85	60	84	105	65
3	11	68	95	70	n.d.	n.d.	n.d.
21	12	60	130	80	76	110	70
12	13	80	140	90	60	130	80
23	14	64	110	70	72	120	60
10	15	112	130	80	84	110	70
11	16	80	130	80	80	125	65
35	17	68	130	80	72	115	65
29	18	72	125	65	72	110	60
40	19	64	110	70	60	110	60
16	20	68	120	70	84	130	70
33	21	60	120	70	72	120	60
39	22	64	110	90	72	100	70
20	23	72	120	70	88	100	60
31	24	60	115	75	72	120	70
38	25	84	135	95	60	130	80
34	26	64	110	65	56	105	60
41	27	60	140	90	80	110	70
6	28	84	140	90	84	120	70
9	29	64	110	70	84	110	60
37	30	72	90	60	76	110	70
4	31	52	140	75	n.d.	n.d.	n.d.
36	32	88	115	70	72	110	70
44	33	84	110	70	68	110	60
46	34	80	125	90	79	110	50

Abbreviations: n.d. – not done

Table 15.2.17 Individual patient date listing of physical examination.

A standard physical examination was done at the screening and the last visit and if needed. The following inspections were included: hair and skin; lymph nodes; eyes; nose, ears and throat; chest; respiratory; heart; abdomen; musculoskeletal, neurological; assessed as normal, abnormal or were not done. The inspection of the urogenital and rectal tract was never done.

S- No.	P- No.	Observation	Complete physical examination	Comment, Abnormalities
14	1	Screen, V5	Yes	

18	2	Screen, V5	Yes	
22	3	Screen, V5	Yes	
7	4	Screen, V5	Yes	
19	5	Screen, V5	Yes	
32	6	Screen, V5	Yes	eczema on the back, 4-tongue plaque
13	7	Screen, V5	Yes	
28	8	Screen, V5	Yes	
1	9	Screen, V5, UV	Yes	
30	10	Screen, V5	Yes	atypical naevus
3	11	Screen, V5	Yes	
21	12	Screen, V5	Yes	
12	13	Screen, V5	Yes	haemangioma tongue
23	14	Screen, V5	Yes	
10	15	Screen, V5	Yes	epilepsy is known
11	16	Screen, V5	Yes	
35	17	Screen, V5	Yes	
29	18	Screen, V5	Yes	
40	19	Screen, V5	Yes	
16	20	Screen, V5	Yes	
33	21	Screen, V5	Yes	
39	22	Screen, V5	Yes	
20	23	Screen, V5	Yes	
31	24	Screen, V5	Yes	nevus-cell-nevus left mamma
38	25	Screen, V5	Yes	
34	26	Screen, V5	Yes	
41	27	Screen, V5	Yes	
6	28	Screen, V5	Yes	
9	29	Screen, V5	Yes	
37	30	Screen, V5	Yes	
4	31	Screen, V5	Yes	myopic
36	32	Screen, V5	Yes	
44	33	Screen, V5	Yes	red throat
46	34	Screen, V5	Yes	

S-No. = Screening number, P-No. = Patient number, V = Visit, FU = Follow Up, UV = Unscheduled Visit

Table 15.2.18 Individual patient data listing demographic information and adherence to inclusion and exclusion criteria

S-No.	P-No.	Age (years)	Sex	Height (cm)	Weight (kg)	Ethnic group	Adherence to inclusion and exclusion criteria
14	1	35	male	186	70	caucasian	yes
18	2	25	female	170	54	caucasian	yes
22	3	36	male	173	88	caucasian	yes
7	4	46	female	170	60	caucasian	yes
19	5	35	male	183	89	caucasian	yes
32	6	42	male	183	73	caucasian	yes
13	7	20	male	179	70	caucasian	yes
28	8	35	male	174	72	caucasian	yes
1	9	50	female	165	66	caucasian	yes
30	10	40	female	168	55	caucasian	yes
3	11	47	female	167	66	caucasian	yes
21	12	49	female	164	60	caucasian	yes
12	13	54	male	183	82	caucasian	yes

23	14	26	female	174	80	caucasian	yes
10	15	25	female	162	75	caucasian	yes
11	16	20	male	182	66	caucasian	yes
35	17	43	male	185	88	caucasian	yes
29	18	42	female	171	79	caucasian	yes
40	19	51	female	170	66	caucasian	yes
16	20	20	male	169	75	caucasian	yes
33	21	45	female	162	58	caucasian	yes
39	22	44	female	165	62	caucasian	yes
20	23	22	female	170	68	caucasian	yes
31	24	23	female	180	75	caucasian	yes
38	25	45	male	181	84	caucasian	yes
34	26	35	female	162	51	caucasian	yes
41	27	49	male	178	93	caucasian	yes
6	28	29	female	168	78	caucasian	yes
9	29	46	female	162	66	caucasian	yes
37	30	30	female	166	53	caucasian	yes
4	31	19	male	182	75	caucasian	yes
36	32	22	male	190	72	caucasian	yes
44	33	24	female	178	66	caucasian	yes
46	34	22	female	156	53	caucasian	yes
2	SF	19	female	171	65	caucasian	no
5	SF	44	male	n.d.	n.d.	n.d.	no
8	SF	37	male	185	78	caucasian	no
15	SF	47	male	180	80	caucasian	no
17	SF	n.d.	n.d.	n.d.	n.d.	n.d.	no
24	SF	28	male	183	80	caucasian	no
25	SF	28	female	n.d.	n.d.	caucasian	no
26	SF	32	female	n.d.	n.d.	caucasian	no
27	SF	23	female	164	61	caucasian	no
42	SF	46	male	178	72	caucasian	no
43	SF	56	female	165	58	caucasian	no
45	SF	20	male	184	73	caucasian	no

Table 15.2.19 Individual patient data listing of tolerability assessed by patient and investigator

P-No.	Tolerability assessed by patient				Tolerability assessed by investigator			
	very well	well	moderate	poorly	very well	well	moderate	poorly
1*	x				x			
2	x					x		
3*	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
4		x				x		
5	x				x			
6	x				x			
7		x				x		
8		x				x		
9			x			x		
10		x				x		
11	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
12				x			x	
13	x				x			
14	x					x		

15	x					x		
16		x				x		
17			x			x		
18	x				x			
19	x				x			
20	x				x			
21		x				x		
22		x				x		
23	x				x			
24	x				x			
25	x					x		
26	x				x			
27		x				x		
28	x				x			
29	x				x			
30*				x			x	
31*	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
32		x				x		
33	x				x			
34		x				x		

n.d. = not done; * excluded from PP