

# REVIEW OF DATA LISTINGS

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Consultancy for a company	X				
Strategic advisory role for a company	X				
Financial interests	X				
Ownership of a patent	X				
Indirect interests:					
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Investigator	X				
Individual's Institution/Organisation receives a grant or other funding	x				

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NOTE: I do not receive any compensation for this presentation



## Reference texts

- **EudraLex Vol.10** - Guidance for the preparation of good clinical practice inspections- May 2008
- **ICH Topic E3** - Note for guidance on structure and content of clinical study reports (CPMP/ICH/137/95)- July 1996

# From the Centralized Application Procedure (CAP)/EU guidance...

Essential information and documentation required for preparing the inspection need to be identified, obtained and reviewed. The information needed to conduct the inspection, may be derived from a number of sources e.g. the (CHMP) inspection request, MA dossier, reference documents, guidelines, legislation, inspection SOPs (EU, local), international standards (ISO/NEN), local legal requirements (EU, third country), local field standards, additional documents requested from the sponsor/inspectees etc.

Results of the documentation review have to be incorporated into the **inspection plan(s)**

# From the CAP procedure/EU guidance...

Inspection plan(s) generally outline and define the relevant aspects of the clinical trial site(s) and scope that are to be covered during the inspection at the selected site(s). It is based on the (adopted CHMP) inspection request and the reviewed documentation.

A check list may be designed as part of the local inspection plan



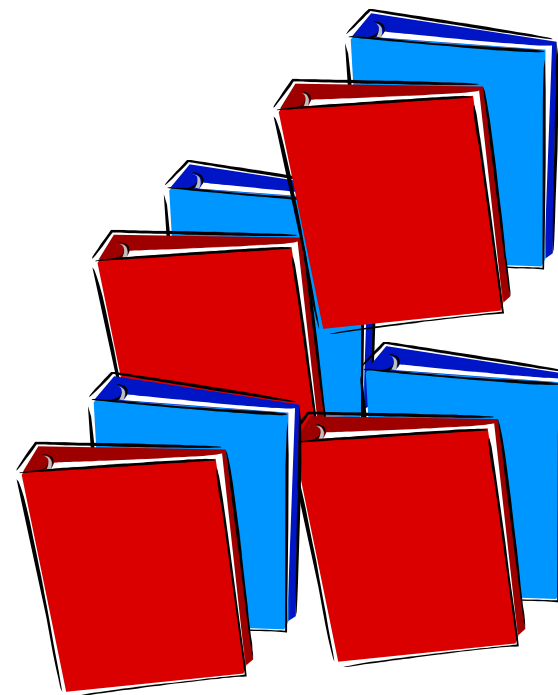
# From the CAP procedure/EU guidance...

*Appendix 1: documents/information that may be used for review prior to the start of the inspection*

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## 10.Data tabular listings of individual data

- per site
- per criteria





# ICH Topic E3 Note for guidance on structure and content of clinical study reports

## 16 Appendices

### 16.2. PATIENT DATA LISTINGS

16.2.1 Discontinued patients

16.2.2 Protocol deviations

16.2.3 Patients excluded from the efficacy analysis

16.2.4 Demographic data

16.2.5 Compliance and/or drug concentration data (if available)

16.2.6 Individual efficacy response data

16.2.7 Adverse event listings (each patient)

16.2.8. Listing of individual laboratory measurements by patient, when required by regulatory authorities



# An example of GCP-CHPM request

The inspectors are asked in particular to focus on confirming:

- The existence of the patients
- The availability of informed consent for each patient in the sample and the procedure to obtain this consent
- Verification of the information/training received by the subjects for the completion of the diary card
- Adherence to inclusion and exclusion criteria
- Source data verification on baseline data and efficacy primary/secondary endpoints and safety
- Verification of the administration of study medication and accountability
- Reporting of SAEs
- Confirmation of the monitoring of the study by the sponsor



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## 16.2. PATIENT DATA LISTINGS

16.2.1 Discontinued patients

16.2.2 Protocol deviations

16.2.3 Patients excluded from the efficacy analysis

16.2.4 Demographic data

16.2.5 Compliance and/or drug concentration data (if available)

16.2.6 Individual efficacy response data

16.2.7 Adverse event listings (each patient)

16.2.8 Listing of individual laboratory measurements by patient, when required by regulatory authorities

Verify the existence of the patients.

The availability of informed consent for each patient in the sample and the procedure to obtain this consent

Adherence to inclusion and exclusion criteria.

Source data verification on baseline data and efficacy primary/secondary endpoints and safety.

Verification of the administration of study medication administration / accountability and how the blinding was ensured.

Reporting of SAEs

Confirmation of the monitoring of the study by the sponsor.



## *Some examples...*

Appendix 16.2.1.1

Listing of Study Terminations

Site :

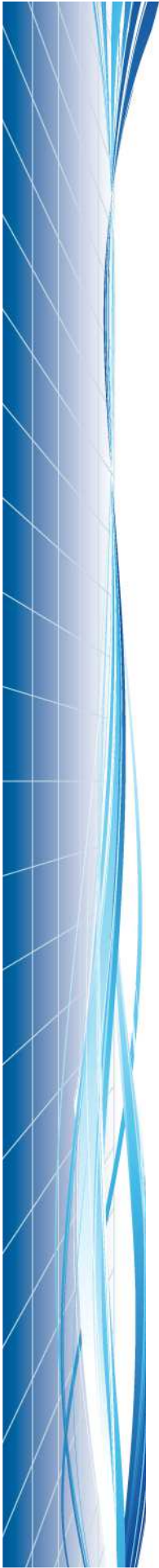
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Site/ Subject	Group	Study Withdrawal Date	Day of Study	Study Withdrawal Reason(s) (Description)
03/062		28APR06	22	PROTOCOL DEVIATION/VIOLATION (PREGNANCY)
03/073		09MAY06	25	LOST TO FOLLOW-UP
03/081		09MAY06	22	WITHDRAWAL OF CONSENT
03/086		12MAY06	24	WITHDRAWAL OF CONSENT
03/342		28APR06	25	WITHDRAWAL OF CONSENT
03/345		27APR06	23	WITHDRAWAL OF CONSENT
03/350		28APR06	23	WITHDRAWAL OF CONSENT
03/370		09MAY06	22	WITHDRAWAL OF CONSENT




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Appendix 16.2.2.1

Listing of Protocol Deviations - CENTER 05

Site/Subject	Group	Deviation	Subset	Reason/s
05/003		Minor		Enrolled in the study despite Hyperthyroidism
05/035		Minor		Enrolled in the study despite Asthma
05/041		Minor		Enrolled in the study despite Asthma
05/045		Minor		Enrolled in the study despite Asthma
05/046		Minor		Enrolled in the study despite Asthma
05/063		Minor		Enrolled in the study despite Asthma

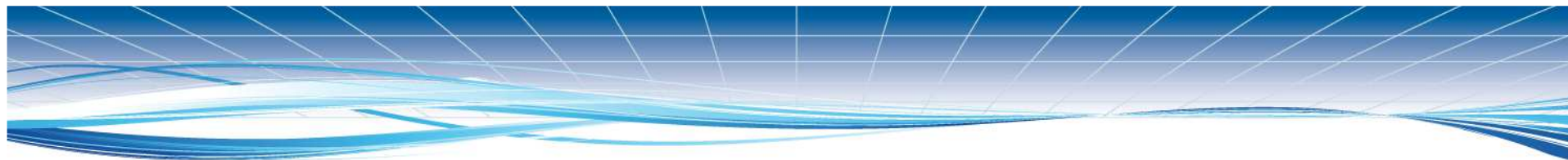
# Appendix 16.2.4.1

## Listing of Demography - CENTER 04

Site: 04

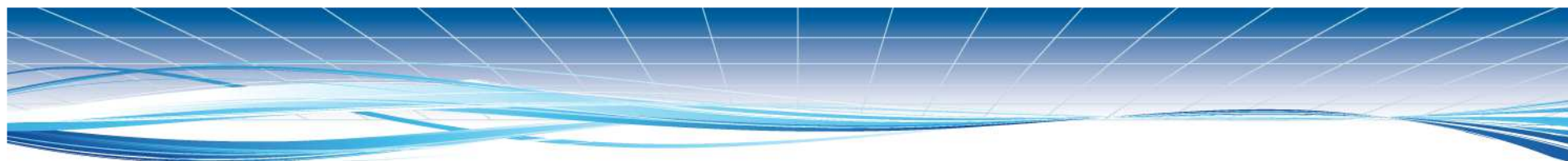
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Site/Subject Group	Age (Years)	Sex	Race	Weight (kg)	Height (cm)	Meeting Entry Criteria?
04/034	30	FEMALE	CAUCASIAN	65.0	160	NO
04/035	40	MALE	CAUCASIAN	80.0	168	NO
04/036	32	MALE	CAUCASIAN	98.0	188	YES
04/037	24	FEMALE	CAUCASIAN	48.0	160	NO
04/038	44	FEMALE	CAUCASIAN	62.0	160	NO
04/039	19	FEMALE	CAUCASIAN	65.0	165	NO
04/040	18	FEMALE	CAUCASIAN	57.0	165	NO
04/041	23	FEMALE	CAUCASIAN	61.0	175	NO
04/042	44	FEMALE	CAUCASIAN	55.0	170	NO
04/043	32	FEMALE	CAUCASIAN	70.0	168	NO
04/044	43	FEMALE	CAUCASIAN	63.0	160	NO
04/045	26	FEMALE	CAUCASIAN	69.0	162	NO
04/046	27	MALE	CAUCASIAN	103.5	196	NO
04/047	31	MALE	CAUCASIAN	78.0	168	NO
04/048	29	FEMALE	CAUCASIAN	79.0	168	NO
04/049	22	MALE	CAUCASIAN	72.0	185	NO
04/050	24	FEMALE	CAUCASIAN	69.0	165	NO
04/051	21	FEMALE	CAUCASIAN	64.0	155	NO
04/052	24	FEMALE	CAUCASIAN	53.0	160	NO
04/053	23	MALE	CAUCASIAN	78.5	172	NO
04/054	25	MALE	CAUCASIAN	80.0	175	NO
04/055	24	MALE	CAUCASIAN	70.0	182	NO
04/056	18	MALE	CAUCASIAN	66.0	185	NO
04/057	50	FEMALE	CAUCASIAN	53.0	160	NO
04/058	51	MALE	CAUCASIAN	84.5	175	NO
04/059	40	FEMALE	CAUCASIAN	53.0	160	YES
04/060	43	MALE	CAUCASIAN	73.0	172	NO
04/061	38	FEMALE	CAUCASIAN	88.0	171	NO
04/062	18	MALE	CAUCASIAN	85.0	186	NO
04/063	18	MALE	CAUCASIAN	100.0	187	NO
04/064	45	FEMALE	CAUCASIAN	90.0	175	NO
04/065	18	MALE	CAUCASIAN	65.0	173	NO
04/066	18	MALE	CAUCASIAN	60.0	176	NO



Weight-Height	N. Subject	Age	N. Subject	Age	Total subj.
<b>53-164</b>	<b>68</b>	<b>18</b>	<b>229</b>	<b>18</b>	<b>2</b>
<b>67-172</b>	<b>110</b>	<b>20</b>	<b>182</b>	<b>21</b>	<b>2</b>
<b>70-186</b>	<b>105</b>	<b>27</b>	<b>225</b>	<b>28</b>	<b>2</b>
<b>55-156</b>	<b>95</b>	<b>20</b>	<b>238</b>	<b>30</b>	<b>2</b>
<b>57-156</b>	<b>163</b>	<b>18</b>	<b>237</b>	<b>30</b>	<b>2</b>
<b>52-158</b>	<b>247</b>	<b>22</b>	<b>113</b>	<b>30</b>	<b>2</b>
<b>58-168</b>	<b>168</b>	<b>30</b>	<b>191</b>	<b>31</b>	<b>2</b>
<b>68-165</b>	<b>50</b>	<b>24</b>	<b>23</b>	<b>31</b>	<b>2</b>
<b>72-170</b>	<b>136</b>	<b>27</b>	<b>239</b>	<b>34</b>	<b>2</b>
<b>64-164</b>	<b>171</b>	<b>29</b>	<b>205</b>	<b>37</b>	<b>2</b>
<b>50-164</b>	<b>124</b>	<b>18</b>	<b>200</b>	<b>37</b>	<b>2</b>
<b>65-165</b>	<b>39</b>	<b>19</b>	<b>139</b>	<b>40</b>	<b>2</b>
<b>56-167</b>	<b>77</b>	<b>18</b>	<b>28</b>	<b>40</b>	<b>2</b>
<b>95-180</b>	<b>162</b>	<b>34</b>	<b>21</b>	<b>41</b>	<b>2</b>





Weight-Height	N. Subject	Age	N. Subject	Age	N. Subject	Age	N. Subject	Age	Total subj.
55-170	67	20	42	44					2
80-180	14	19	198	47					2
70-182	55	24	166	47					2
52-161	243	22	230	49					2
60-164	143	36	99	49					2
70-170	190	45	153	50					2
80-168	35	40	152	50					2
53-160	52	24	224	31	59	40	57	50	4
50-160	24	29	126	44	179	51	219	51	4
56-162	242	23	135	51					2
80-175	173	36	58	51					2
56-164	217	20	137	37	192	52			3
74-170	71	24	177	52					2
70-165	43	52	89	52	78	21			3



## Listing of Subject Vaccination Data - CENTER 05

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Site/Subject Group	Immunization #	Date of Immunization	Pre-Immunization axillary Temperature (C)	Temperature Location	Study day	Time of Injection	Site of Injection
05/067	1	24FEB07	36.8	AXILLARY	1	10:18	L DELTOID
05/068	2	17MAR07	36.8	AXILLARY	22	9:28	L DELTOID
05/069	1	24FEB07	36.6	AXILLARY	1	10:40	L DELTOID
05/069	2	17MAR07	37.1	AXILLARY	22	12:30	L DELTOID
05/070	1	24FEB07	36.7	AXILLARY	1	11:38	L DELTOID
05/070	2	17MAR07	36.2	AXILLARY	22	12:50	L DELTOID
05/071	1	24FEB07	36.8	AXILLARY	1	11:40	L DELTOID
05/071	2	17MAR07	36.5	AXILLARY	22	11:58	L DELTOID
05/072	1	24FEB07	37.0	AXILLARY	1	12:10	L DELTOID
05/072	2	17MAR07	37.0	AXILLARY	22	10:50	L DELTOID
05/073	1	24FEB07	36.3	AXILLARY	1	12:00	L DELTOID
05/073	2	17MAR07	36.4	AXILLARY	22	12:00	L DELTOID
05/074	1	24FEB07	36.6	AXILLARY	1	13:20	L DELTOID
05/074	2	17MAR07	36.7	AXILLARY	22	9:45	L DELTOID
05/075	1	24FEB07	36.4	AXILLARY	1	13:20	L DELTOID
05/075	2	17MAR07	36.4	AXILLARY	22	9:45	L DELTOID
05/076	1	24FEB07	37.0	AXILLARY	25	9:10	L DELTOID
05/076	2	20MAR07	37.1	AXILLARY	24	14:00	L DELTOID
05/077	1	24FEB07	37.1	AXILLARY	1	10:45	L DELTOID
05/077	2	20MAR07	36.6	AXILLARY	22	10:40	R DELTOID
05/078	1	24FEB07	36.8	AXILLARY	1	11:00	L DELTOID
05/078	2	20MAR07	36.8	AXILLARY	25	11:30	L DELTOID
05/079	1	24FEB07	37.0	AXILLARY	1	11:35	L DELTOID
05/080	1	24FEB07	36.7	AXILLARY	23	10:30	L DELTOID
05/081	1	24FEB07	36.5	AXILLARY	1	14:30	L DELTOID
05/081	2	20MAR07	36.6	AXILLARY	22	14:00	L DELTOID
05/082	1	24FEB07	36.7	AXILLARY	1	14:48	L DELTOID
05/082	2	20MAR07	36.8	AXILLARY	22	15:00	L DELTOID
05/083	1	24FEB07	36.9	AXILLARY	1	14:58	R DELTOID
05/083	2	20MAR07	36.8	AXILLARY	22	15:10	R DELTOID

### Listing of subjects divided for vaccination times and dates site 04

Date of in	Subject n	Immuniza	Time of Iniecton		
09-mar-07	04/071	2°	7.50		
09-mar-07	04/075	2°	7.30		
09-mar-07	04/081	2°	14.10		
09-mar-07	04/082	2°	14.00		
09-mar-07	04/217	1°	13.00		
09-mar-07	04/218	1°	13.10		
09-mar-07	04/219	1°	13.00		
09-mar-07	04/220	1°	15.15		
<b>TOT 8</b>					
11-mar-07	04/090	2°	15.00		
11-mar-07	04/091	2°	15.30		
11-mar-07	04/092	2°	15.15		
<b>TOT 3</b>					
12-mar-07	04/086	2°	12.30		
12-mar-07	04/087	2°	12.40		
12-mar-07	04/093	2°	10.30		
12-mar-07	04/094	2°	10.35		
12-mar-07	04/095	2°	13.05		
12-mar-07	04/096	2°	13.15		
12-mar-07	04/097	2°	10.05		
12-mar-07	04/099	2°	11.00		
12-mar-07	04/100	2°	11.08		
12-mar-07	04/101	2°	11.25		
<b>TOT 10</b>					



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# Appendix 16.2.4.3

Verbatim to Summary Term Mapping for Medical History - CEMER 04

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Medical History Summary Term <sup>1</sup>	Verbatim Term	Site/Subject Numbers
CIRCULATORY SYSTEM	ANGINA PECTORAL STABILE	04/130
	ARRHYTHMIA	04/059
	ARTERIAL HYPERTENSION	04/089, 04/130, 04/201, 04/211
		04/223, 04/235
	HYPERTENSION	04/233
	HYPERTENSION (ARTERIAL)	04/149
ENDOCRINE, NUTRITIONAL, METABOLIC, DAMNITY	HYPERTONIA ARTERIALIS	04/106, 04/107, 04/108, 04/198
	DIABETES MELLITUS	04/118
	HYPERCHOLESTEROLEMIA	04/130
	OBESITY	04/108, 04/133, 04/157, 04/226
	ALLENOMY	04/218
	AORTIC ANEURYSM-STATUS POST SURGERY	04/153
FACTORS INFLUENCING HEALTH STATUS AND CONTACT WITH HEALTH SERVICES	HYSTERECTOMY-UTERINE MYOMA	04/074
	STROMA-STATUS AFTER OPERATION	04/158
	FRACTURE LEFT CLAVICLE	04/096
	FRACTURE THIGH BONE	04/153
INJURY AND POISONING		
NERVOUS SYSTEM AND SENSE ORGANS	GLAUCOMA	04/120
	LEFT SHOULDER-HAND SYNDROME	04/058
RESPIRATORY SYSTEM	PNEUMONIA	04/084
SKIN AND SUBCUTANEOUS TISSUE	ACNE	04/110
	PSORIASIS	04/233
	VERTIGO	04/179
Symptoms, Signs and Ill-Defined Conditions		



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## Listing of Reactogenicity - CENTER 04

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Immunization		Injection Site Reactions				Systemic Reactions							Temp. (C)	Stay Home	Analgesic Antipyretic Med.Used	
No.	Date	Erythema (mm)	Induration (mm)	Swelling (mm)	Erythema (mm)	Pain	Chills	Malaise	Myalgia	Arthralgia	Headache	Sneezing				Fatigue
...Continued from previous page																
Site/Subject: 04/145																
1	26FEB07	0	0	0	0	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NO
	7 DAYS	0	0	0	0	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NO
2	19APR07	0	0	0	0	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NO
	30 MINUTES	0	0	0	0	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NO
	6 HOURS	0	0	0	0	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NO
	2 DAYS	0	0	0	0	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NO
	3 DAYS	0	0	0	0	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NO
	4 DAYS	0	0	0	0	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NO
	5 DAYS	0	0	0	0	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NO
	6 DAYS	0	0	0	0	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NO
	7 DAYS	0	0	0	0	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NO
Site/Subject: 04/146																
1	26FEB07	0	0	0	0	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NO
	30 MINUTES	0	0	0	0	MILD	MILD	MILD	MILD	MILD	MILD	NONE	NONE	MILD	NONE	NO
	6 HOURS	0	0	0	0	MILD	MILD	MILD	MILD	MILD	MILD	NONE	NONE	MILD	NONE	NO
	2 DAYS	0	25	25	25	MILD	MILD	MILD	MILD	MILD	MILD	MILD	MILD	MILD	NONE	NO
	3 DAYS	0	25	25	25	MILD	MILD	MILD	MILD	MILD	MILD	MILD	MILD	MILD	NONE	NO
	4 DAYS	0	15	15	15	MILD	MILD	MILD	MILD	MILD	MILD	NONE	MILD	MILD	NONE	NO
	5 DAYS	0	5	5	5	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NO
	6 DAYS	0	0	0	0	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NO
	7 DAYS	0	0	0	0	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NO
2	19APR07	0	0	0	0	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NO
	30 MINUTES	0	0	0	0	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NONE	NO
	6 HOURS	0	0	0	0	MILD	SEV	SEV	SEV	SEV	SEV	MILD	SEV	SEV	NONE	NO

Continued on next page ....



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# Appendix 16.2.5.1

## Listing of Subject Vaccination Data

Site/Subject Group	Immunization #	Date of Immunization	Pre-Immunization Temperature (C)	Temperature Location	Study day	Time of Injection	Site of Injection
01/340	1	11MAY06	36.5	AXILLARY	1	16:05	R DELTOID
01/341	2	01JUN06	36.4	AXILLARY	22	10:20	R DELTOID
01/341	1	12MAY06	36.4	AXILLARY	1	13:05	L DELTOID
01/342	2	01JUN06	36.0	AXILLARY	21	9:50	L DELTOID
01/342	1	19MAY06	36.0	AXILLARY	1	9:05	L DELTOID
01/343	2	05JUN06	36.1	AXILLARY	22	9:55	L DELTOID
01/343	1	17MAY06	36.2	AXILLARY	1	9:55	L DELTOID
01/344	2	07JUN06	36.1	AXILLARY	22	10:35	L DELTOID
01/344	1	17MAY06	36.2	AXILLARY	22	9:35	L DELTOID
01/345	2	07JUN06	36.2	AXILLARY	22	7:50	L DELTOID
01/345	1	22MAY06	36.1	AXILLARY	1	7:50	L DELTOID
01/346	2	12JUN06	36.2	AXILLARY	22	7:35	L DELTOID
01/346	1	22MAY06	36.1	AXILLARY	22	11:45	L DELTOID
01/347	2	14JUN06	36.0	AXILLARY	34	10:10	L DELTOID
01/347	1	23MAY06	36.5	AXILLARY	1	10:10	L DELTOID
01/347	2	13JUN06	36.4	AXILLARY	22	7:35	L DELTOID
01/347	1	23MAY06	36.5	AXILLARY	1	10:05	L DELTOID
01/348	2	13JUN06	36.2	AXILLARY	22	7:50	L DELTOID
01/348	1	23MAY06	36.0	AXILLARY	1	11:35	L DELTOID
01/349	2	13JUN06	35.9	AXILLARY	22	9:30	L DELTOID
01/349	1	29MAY06	36.0	AXILLARY	1	7:35	L DELTOID
01/350	2	15JUN06	36.3	AXILLARY	22	9:05	L DELTOID
01/351	2	29MAY06	36.0	AXILLARY	1	9:30	L DELTOID
01/352	2	15JUN06	36.2	AXILLARY	22	10:45	L DELTOID
01/352	1	29MAY06	36.2	AXILLARY	1	10:50	L DELTOID
01/353	2	15JUN06	36.1	AXILLARY	22	9:45	L DELTOID
01/353	1	29MAY06	36.5	AXILLARY	1	11:25	L DELTOID
01/354	2	15JUN06	36.0	AXILLARY	22	10:30	L DELTOID
01/354	1	29MAY06	36.1	AXILLARY	1	7:35	L DELTOID
01/355	2	16JUN06	36.0	AXILLARY	22	9:05	L DELTOID
01/355	1	28MAY06	36.2	AXILLARY	1	9:10	L DELTOID
01/356	2	16JUN06	35.7	AXILLARY	21	7:45	L DELTOID
01/356	1	28MAY06	35.6	AXILLARY	1	12:20	L DELTOID
01/356	2	16JUN06	36.0	AXILLARY	22	7:50	L DELTOID



## Listing of Blood Draw Data

Site: 01

Site/Subject Group	Day 1				Day 22				Day 43			
	Blood Draw Date	Blood Draw time	Not Done Box	Between Day 1 & 22 (study days)	Blood Draw Date	Blood Draw time	Not Done Box	Between Day 1 & 22 (study days)	Blood Draw Date	Blood Draw time	Not Done Box	Between Day 1 & 43 (study days)
01/332	06MAY06	12:45	NO		26MAY06	12:55	NO	23	15JUN06	12:00	NO	43
01/333	06MAY06	9:30	NO		30MAY06	10:00	NO	23	21JUN06	11:00	NO	45
01/334	06MAY06	9:30	NO		01JUN06	8:45	NO	24	21JUN06	8:15	NO	44
01/335	10MAY06	12:15	NO		31MAY06	10:45	NO	22	21JUN06	9:00	NO	43
01/336	10MAY06	11:20	NO		31MAY06	8:40	NO	22	21JUN06	9:30	NO	43
01/337	10MAY06	12:00	NO		31MAY06	9:00	NO	22	21JUN06	9:15	NO	43
01/338	11MAY06	11:40	NO		01JUN06	9:30	NO	22	22JUN06	9:05	NO	43
01/339	11MAY06	14:15	NO		01JUN06	14:40	NO	22	22JUN06	14:35	NO	42
01/340	11MAY06	16:00	NO		01JUN06	10:15	NO	22	22JUN06	8:30	NO	43
01/341	12MAY06	11:00	NO		01JUN06	8:45	NO	21	22JUN06	8:15	NO	42
01/342	15MAY06	9:00	NO		05JUN06	8:45	NO	22	26JUN06	8:15	NO	43
01/343	15MAY06	9:50	NO		07JUN06	8:45	NO	22	25JUN06	8:30	NO	43
01/344	15MAY06	10:30	NO		08JUN06	8:30	NO	22	29JUN06	8:00	NO	43
01/345	22MAY06	8:45	NO		12JUN06	8:30	NO	22	06JUL06	9:15	NO	46
01/346	22MAY06	11:15	NO		14JUN06	10:05	NO	24	06JUL06	12:50	NO	46
01/347	22MAY06	10:25	NO		13JUN06	8:30	NO	22	04JUL06	9:00	NO	43
01/348	22MAY06	10:00	NO		13JUN06	8:45	NO	22	04JUL06	9:15	NO	43
01/349	22MAY06	11:30	NO		13JUN06	8:30	NO	22	09JUL06	10:05	NO	42
01/350	25MAY06	8:30	NO		15JUN06	9:00	NO	22	07JUL06	8:30	NO	44
01/351	25MAY06	9:45	NO		15JUN06	10:40	NO	22	06JUL06	9:00	NO	43
01/352	25MAY06	10:45	NO		15JUN06	9:40	NO	22	07JUL06	9:30	NO	44
01/353	25MAY06	11:45	NO		15JUN06	10:25	NO	22	07JUL06	10:15	NO	44
01/354	26MAY06	8:30	NO		16JUN06	8:30	NO	22	07JUL06	8:15	NO	43
01/355	26MAY06	8:05	NO		15JUN06	8:40	NO	21	06JUL06	8:45	NO	42
01/356	26MAY06	12:15	NO		16JUN06	8:45	NO	22	07JUL06	8:50	NO	43
01/357	26MAY06	5:40	NO		16JUN06	8:35	NO	22	07JUL06	10:35	NO	43
01/358	26MAY06	13:15	NO		20JUN06	12:50	NO	23	11JUL06	17:35	NO	44
01/359	26MAY06	17:10	NO		20JUN06	12:30	NO	23	10JUL06	16:00	NO	43
01/360	30MAY06	9:00	NO		20JUN06	8:25	NO	22	13JUL06	10:00	NO	45
01/361	30MAY06	14:45	NO		20JUN06	15:20	NO	22	11JUL06	15:25	NO	43
01/362	30MAY06	15:05	NO		20JUN06	15:30	NO	22	11JUL06	15:15	NO	43
01/363	31MAY06	12:30	NO		21JUN06	12:30	NO	22	11JUL06	12:45	NO	42





# Appendix 16.2.5.1

## Listing of Subject Vaccination Data

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Site/Subject Group	Immunisation #	Date of Immunisation	Pre-Immunisation Temperature (°C)	Temperature Location	Study day	Time of Injection	Site of Injection
01/340	1	11MAY06	36.5	AXILLARY	1	16:05	R DELTOID
	2	01JUN06	36.4	AXILLARY	22	10:20	R DELTOID
01/341	1	12MAY06	36.4	AXILLARY	1	11:05	L DELTOID
	2	01JUN06	36.0	AXILLARY	21	9:50	L DELTOID
01/342	1	19MAY06	36.0	AXILLARY	1	9:05	L DELTOID
	2	05JUN06	36.1	AXILLARY	22	8:50	L DELTOID
01/343	1	17MAY06	36.2	AXILLARY	1	9:55	L DELTOID
	2	07JUN06	36.1	AXILLARY	22	8:50	L DELTOID
01/344	1	18MAY06	36.2	AXILLARY	1	10:35	L DELTOID
	2	05JUN06	36.2	AXILLARY	22	9:35	L DELTOID
01/345	1	22MAY06	36.1	AXILLARY	1	8:50	L DELTOID
	2	12JUN06	36.2	AXILLARY	22	8:35	L DELTOID
01/346	1	22MAY06	36.1	AXILLARY	1	11:45	L DELTOID
	2	14JUN06	36.0	AXILLARY	24	10:10	L DELTOID
01/347	1	23MAY06	36.5	AXILLARY	1	10:30	L DELTOID
	2	13JUN06	36.4	AXILLARY	22	8:35	L DELTOID
01/348	1	28MAY06	36.5	AXILLARY	1	10:05	L DELTOID
	2	13JUN06	36.2	AXILLARY	22	8:50	L DELTOID
01/349	1	23MAY06	36.0	AXILLARY	1	11:35	L DELTOID
	2	13JUN06	35.9	AXILLARY	22	9:30	L DELTOID
01/350	1	29MAY06	36.0	AXILLARY	1	8:35	L DELTOID
	2	15JUN06	36.3	AXILLARY	22	9:05	L DELTOID
01/351	1	29MAY06	36.0	AXILLARY	1	9:50	L DELTOID
	2	15JUN06	36.2	AXILLARY	22	10:45	L DELTOID
01/352	1	29MAY06	36.2	AXILLARY	1	10:50	L DELTOID
	2	15JUN06	36.1	AXILLARY	22	9:45	L DELTOID
01/353	1	29MAY06	36.5	AXILLARY	1	11:25	L DELTOID
	2	15JUN06	36.0	AXILLARY	22	10:30	L DELTOID
01/354	1	26MAY06	36.1	AXILLARY	1	8:35	L DELTOID
	2	16JUN06	36.0	AXILLARY	22	9:05	L DELTOID
01/355	1	26MAY06	36.2	AXILLARY	1	9:10	L DELTOID
	2	15JUN06	35.8	AXILLARY	21	8:45	L DELTOID
01/356	1	26MAY06	35.6	AXILLARY	1	12:20	L DELTOID
	2	16JUN06	36.0	AXILLARY	22	8:50	L DELTOID



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01/344	17MAY06	15 MAY 06	36.2	AXILLARY	1	10:35
01/345	07JUN06	1 MAY 06	36.2	AXILLARY	22	9:15
01/346	22MAY06		36.1	AXILLARY	1	7:50 CEF 8.50
01/347	12JUN06		36.2	AXILLARY	22	7:15 " 8.35
	22MAY06		36.1	AXILLARY	1	11:45
	14JUN06		36.0	AXILLARY	24	10:10
	23MAY06		36.5	AXILLARY	1	10:30
	13JUN06		36.4	AXILLARY	22	7:35 CEF 8.35
	23MAY06		36.5	AXILLARY	1	10:05
	13JUN06		36.2	AXILLARY	22	7:50 CEF 8.50
	23MAY06		36.0	AXILLARY	1	11:15
	13JUN06		35.9	AXILLARY	22	9:30
01/350	25MAY06		36.0	AXILLARY	1	7:35 CEF 8.35
	15JUN06		36.3	AXILLARY	22	9:05



01/344	19MAY06		36.2	AXILLARY	1	10:35
01/345	09JUN06		36.2	AXILLARY	22	9:35
01/346	22MAY06		36.1	AXILLARY	1	8:50
01/346	12JUN06		36.2	AXILLARY	22	8:35
01/347	22MAY06		36.1	AXILLARY	1	11:45
01/347	14JUN06		36.0	AXILLARY	24	10:10
01/347	23MAY06		36.5	AXILLARY	1	10:30
01/348	13JUN06		36.4	AXILLARY	22	8:35
01/348	23MAY06		36.5	AXILLARY	1	10:05
01/349	13JUN06		36.2	AXILLARY	22	8:50
01/349	23MAY06		36.0	AXILLARY	1	11:45
01/349	13JUN06		35.9	AXILLARY	22	9:30
01/349	23MAY06		36.0	AXILLARY	22	9:05



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# Inspection plan

## **B. [REDACTED] site- Aspects to be inspected**

**DO NOT FORGET APPENDIX 16.2.10.1 FOR LISTING OF COMMENT**

### **Drop-out**

051, 081, 301, 331 (withdrawal of consent)

### **Subjects selected for Medical history**

1. 055 → hyperhomocysteinemia and TIA
2. 073 → Lymphoma non Hodgking (see above monitoring visit 12-13 July 2006)
3. 095 → Epilepsy
4. 097 → Mitral Stenosis
5. 312 → Renal cancer (verify why subject took ibesartan for renal cancer)
6. 314 → Melanoma
7. 324 → Melanoma
8. 339 → TIA
9. 363 → Suprarenal microadenoma
10. 366 → TIA

### **Subject selected for EA**

11. 010 → different EA+ see below monitoring visit on 6-7 April 2006
12. 013 → different EA
13. 040 → lymphadenopathy possibly related
14. 046 → Sev. and mod. EA
15. 315 → haematuria possibly related
16. 335 → different EA



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### **Subjects to verify for ORS:**

17. 003→ See appendix 16.2.7.1.2
18. 039→ See appendix 16.2.7.1.2
19. 052→ See appendix 16.2.7.1.2
20. 066→ See appendix 16.2.7.1.2
21. 074→ See appendix 16.2.7.1.2
22. 091→ See appendix 16.2.7.1.2
23. 093→ See appendix 16.2.7.1.2
24. 304→ See appendix 16.2.7.1.2
25. 332→ See appendix 16.2.7.1.2

### **Subjects that could be selected for Medical history (?)**

1. 017→ Substitution valve mitralic and rheumatic fever
2. 041→ Uterine fibroma removed and other pathology
3. 044→ hemolytic anemias
4. 326→ prostatectomy
5. 351→ diabetes, hypercholesterolemia, hypertension
6. 352→ diabetes, hypercholesterolemia, hypertension
7. 355→ TIA

### **Subjects that could be selected for EA (?)**

015, 018, 063, 066, 067, 344, 357



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### Issues to verify:

1. 001→ in the appendix 16.2.9.1 is recorded acetylcysteine for cough at day 1 after administrative but this EA is not reported in the appendix 16.2.7.1.1.
2. 026→ verify why subject took ibuprofen on 23 and 25 April 2006
3. 030→ verify why subject took aspirina on 26 April for malaise
4. 068→ verify headache on day 5
5. 074 →verify why subject took rizatriptan, considered Analgesic
6. 323→verify why subject is not considered ORS+ see above monitoring visit 12-13 July 2006
7. 341→verify why subject had red eye but he is not considered ORS
8. 354→verify why subject had red eye but he is not considered ORS
9. 360→verify why subject had coughing but he is not considered ORS

10. Time of injection compared to blood draw time → see table

Volunteer	time of 1 <sup>st</sup> injection	1 <sup>st</sup> blood draw time	time of 2 <sup>nd</sup> injection	2 <sup>nd</sup> blood draw time
342			7.50	8.45
343			7.50	8.45
345	7.50	8.45	7.35	8.30
347			7.35	8.30
348			7.50	8.45
350	7.35	8.30		
354	7.35	8.30		
355			7.45	8.40
356			7.50	8.45



### Selected subjects listed according to the randomization number

1.	001	in the appendix 16.2.9.1 is recorded acetylcysteine for cough at day 1 after administration, but this EA is not reported in the appendix 16.2.7.1.1.
2.	003	ORS
3.	010	different EA+ see below monitoring visit on 6-7 April 2006 (wrote a wrong date on the IC (27 March instead 28 March))
4.	013	different EA
5.	026	verify why subject took ibuprofen on 23 and 25 April 2006
6.	030	verify why subject took aspirina on 26 April for malaise
7.	039	ORS
8.	040	EA lymphadenopathy possibly related
9.	046	Sev. and mod. EA
10.	051	Drop
11.	052	ORS
12.	055	hyperomocysteinemia and TIA
13.	066	ORS
14.	068	verify headache on day 5
15.	073	Lymphoma non Hodgking (see above monitoring visit 12-13 July 2006)
16.	074	ORS + verify why subject took rizatriptan, considered Analgesic
17.	081	Drop
18.	091	ORS
19.	093	ORS
20.	095	Epilepsy





21.	097	Mitral Stenosys
22.	301	Drop
23.	304	ORS
24.	312	Renal cancer (verify why subject took ibesartan for renal cancer)
25.	314	Melanoma
26.	315	EA haematuria possibly related
27.	323	verify why subject is not considred ORS+ see above monitoring visit 12-13 July 2006 (discrepancy between patient diary and CRF of subject)
28.	324	Melanoma
29.	331	Drop
30.	332	ORS
31.	335	different EA
32.	339	TIA
33.	341	verify why subject had red eye but he is not considred ORS
34.	354	verify why subject had red eye but he is not considred ORS
35.	360	verify why subject had coughing but he is not considred ORS
36.	363	Suprarenal microadenoma
37.	366	TIA
38.		
39.		



# Thank you



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# QUESTIONS



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