

Attachment 8

Amendments to ASCEND Protocol [V6_201103]

New Version File Name: ASCEND Protocol [V7_190504]

Amendments to ASCEND Protocol - Version 7 (19 May 2004)

Page 3 (Contents)

Section 3.3.2	<i>‘...blood sampling...’</i>	changed to	<i>‘...blood and urine sampling...’</i>
Section 3.4.2	<i>‘...1g daily omega -3...’</i>	changed to	<i>‘...1g daily capsules containing omega-3...’</i>
Section 3.6.1	<i>‘...believed to be due...’</i>	changed to	<i>‘...believed with a reasonable probability to be due...’</i>
Appendix 1	Page number changed to 21		
Appendix 2	Page number changed to 25		
References	Page number changed to 26		
Steering & DMC	Page number changed to 29		
Contact details	Page number changed to 29		

Page 7

Section 1.2.2	<i>‘...0.3g of EPA and 0.6g of DHA...’</i>	changed to	<i>‘...0.4g of EPA and 0.3g of DHA...’</i>
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Section 1.2.4	<i>‘...daily dose of 1g of EPA and DHA...’</i>	changed to	<i>‘...daily dose of approximately 1g of omega-3 FA (0.4g EPA and 0.3g DHA)...’</i>
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Section 2.1	<i>‘...1 gram daily omega-3 fatty acids (0.5g EPA, 0.4g DHA)...’</i>	changed to	<i>‘...1 gram capsules containing 90% omega-3 fatty acids (0.41g EPA, 0.34g DHA) daily...’</i>
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Section 2.3.2	<i>‘...Bayer AG...’</i>	changed to	<i>‘...Bayer Healthcare AG...’</i>
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Section 2.4.3	<i>‘...Bayer AG...’</i>	changed to	<i>‘...Bayer Healthcare AG...’</i>
Section 2.4.5	<i>‘...Blood samples...’</i>	changed to	<i>‘...Blood and urine samples...’</i>

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Section 2.4.7 '*...Bayer AG...*' changed to '*...Bayer Healthcare AG...*'

Page 15 (Summary)

Screening '*...Blood samples...*' changed to '*...Blood and urine samples...*'

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Section 3.3.2 '*..blood sampling...*' changed to '*...blood and urine sampling...*'
'*...blood sampling kit...*' changed to '*...blood and urine sampling kit...*'
'*...10ml blood collection...*' changed to '*...5-10ml blood and urine collection...*'
'*...lipids, and markers of renal function...*' changed to '*...lipids and markers of renal function, and urinary albumin/creatinine ratio...*'

Section 3.4.2 '*...1g daily omega-3...*' changed to '*...1g daily capsules containing omega-3...*'

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Section 3.4.2 2nd bullet point : '*...1 gram daily...*' changed to '*...1 daily...*'

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Section 3.6.1 '*...Bayer AG...*' changed to '*...Bayer Healthcare AG...*'

Section 3.7.1 '*...study treatments on HbA1c, lipids and markers of renal function...*' changed to '*...study treatments on blood HbA1c, lipids and markers of renal function, and on urinary albumin/creatinine ratio...*'

Section 3.7.2 '*...using mail-based systems...*' added to end of section heading

Page 22 (Information Leaflet)

'*...the back of the letter...*' changed to '*...the inside of the letter...*'

'*...that he/she is happy with your continuing...*' changed to '*...that they are happy for you to continue in the study...*'

'*...blood taking kit...*' changed to '*...blood and urine sampling kit...*'

'*...and to provide a urine specimen...*' added

Page 23 (Information Leaflet)

'*...taking warfarin (Marevan, Nicoumalone, Sinthrome)...*' changed to '*...taking warfarin (Marevan) or other blood thinning drugs (e.g. Acenocoumarol (Nicoumalone, Sinthrome) or Phenindione)...*'

'*...if you are taking warfarin...*' changed to '*...if you are taking any of these blood thinning drugs...*'

'*...prescribed it...*' changed to '*...prescribed them...*'

Page 24 (Information Leaflet)

'...makers of the aspirin...' changed to *'...makers of the aspirin/placebo...'*

'...Alternatively you can e-mail us on ascend@ctsu.ox.ac.uk...' added

Page 24 (Summary)

'...returned to you with your first pack of study treatment...' changed to *'...returned to you when your first pack of study treatment is sent out...'*

Page 25 (Consent Form)

'...SIGN and DATE the form, and return in the FREEPOST envelope provided...' changed to *'...SIGN and DATE the form using blue or black ink, and return it in the FREEPOST envelope provided...'*

'...confirm you have read...' changed to *'...confirm that you have read...'*

'...Please use blue or black ink...' added alongside signature box

FREEPOST address changed from *'...FREEPOST (OF 364)...OX2 6YZ...'* to *'...FREEPOST NAT13900...OX2 6BR...'*

'...with a copy of this Agreement to Participate for you to keep...' changed to *'...A copy of this Agreement to Participate, for you to keep, will also be mailed...'*

Page 29 (Steering Committee)

'A Farmer' and *'C George'* added to Committee