APPENDIX 3
Induction of asthma – non-smoking adults.
Validation checks on completeness and consistency of the data

1. Study database

Appendix 5 gives a key to the six character codes used for cards and fields on the study database.

'Blank' data (i.e. no data entered) not allowed for any field in any card

'Missing' data not allowed for field: Card DESCR: STYPE

'Not applicable' (NA) data not allowed for any field in the following cards:
CONFND, OTHRES
or for the following fields:

Card DESCR:	TITLE, FTITLE, SSEX, SAGELO, SAGEHI, SRACE, CONT, LOCAT,BEGYR, ENDYR, PUBYR, REFID, OVERL, PRINC, REFGP
Card DESIGN:	POPUL, MEDEXC,OTHEXC, RESPON, NEVSMO,QUEST
Card ASTHMA:	LIFAST, CURAST, NTOT

'Zero' data not allowed for fields:

Card DESCR:	TITLE, FTITLE, SSEX, SRACE, CONT, USSTAT, EUR, ASIA, LOCAT, BEGYR, ENDYR, FINFYR, PUBYR, REFID, ADDREF, OVERL, PRINC, REFGP
Card DESIGN:	STYPE, CONTRL, CONDIS, POPUL, RESPON, NEVSMO, QUEST
Card ASTHMA:	DIAGLS, TIMLAS, INCAST, DESLAS, DIAGCS, TIMCAS, DESCAS, NLAST, NCAST, NTOT

Other checks on card DESCR
If STYPE=2 (prospective), then –
SAGELO ≤ SAGEHI ≤ SAGEHF
Otherwise (CC or CS study) – SAGELO ≤ SAGEHI and SAGEHF NA

Fields USSTAT, EUR, ASIA must be NA except when the value of CONT is 1-NAMER, 2- EUR, 3- ASIA respectively, in which case must be +ve.

If STYPE=2 (prospective), then –
BEGYR ≤ ENDYR ≤ FINFYR
Otherwise (CC or CS study) – BEGYR ≤ ENDYR and FINFYR NA

If OVERL=1, then PRINC must be 1, otherwise a comment must be entered.

If PRINC=1 then REFGP must be same as REF

Other checks on cards DESIGN and MATCH
If STYPE=2,3 (prospective or cross-sectional study), then fields CONTRL, CONDIS, POPCON, MATSEX, MATAGE, MATRACE, MATLOC, MATSES, MATHOS must be NA.

If STYPE=1 (case-control study), then –

Fields CONTRL, MATSEX, MATAGE, MATRACE, MATLOC, MATSES, MATHOS must not be NA.

CONDIS must be NA if and only if CONTRL=1 (i.e. healthy controls)

MATSEX may only be 1 if SSEX=1.

Other checks on card ASTHMA
Fields DIAGLS, TIMLAS, INCAST, DESLAS must be NA if and only if LIFAST=0. Fields FIRAST, REPCAS, DIAGCS, TIMCAS, DESCAS must be NA if and only if CURAST=0.

If NTOT is non-missing, then NLAST < NTOT if LIFAST=1, and NCAST < NTOT if CURAST=1

Other checks on card CONFND
TOTCO must equal the sum of the other fields in the card excluding COREJE (or TOTCO may be missing).

If COREJE=1, then a comment must be entered.

COSEX may only be 1 if SSEX=1 (i.e. both sexes in study)

Other checks on card OTHRES
If any field has the value 1, then a comment must be entered.

2. RR database

Appendix 7 gives a key to the six character codes used for cards and fields on the relative risk database.

'Blank' data (i.e. no data entered) not allowed for any field in any card.

'Missing' data not allowed for any field on the following cards:
RRDEF, RRADJ
or for the following field: Card RRDATA: DERIVE

'Not applicable' (NA) data not allowed for any field in card RRADJ,
or for the following fields:

Card RRDEF:	NRR, RSEX, RAGELO, RAGEHI, RRACE, RASTIM, ONSET, EXPOS, WHESMO, DOSER, MEASEX, UNEXTI, UNEXSO, SOURCE, DERIVE
Card RRADJ:	ADSEX, ADAGE, ADRACE, ADOETS, ADOTHR
Card RRDATA:	CA1, CA0, RR, RRL, RRU, DERIVE

Other checks on card RRDEF
If EXPOS = 1 (i.e. household), then WHOHOU must be +ve; otherwise WHOHOU must be NA.

If EXPOS = 3 (i.e. total), then WHOTOT must be +ve; otherwise WHOTOT must be NA.

ODDSON must be NA if and only if ONSET=0.

If DOSER=1, 11, 12 (i.e. not standard dose-response category) then EXPLO and EXPHI must be NA

If DOSER is in the range 2-10 (i.e. standard dose-response category) then
MEASEX >0
EXPLO, EXPHI must not be NA
EXPLO #EXPHI
UNEXHI # EXPLO

UNEXHI may be NA if and only if MEASEX=1 (i.e. not dose-response, and not denominator is "low" exposure), except if DOSER=11.

Either both RAGELO = RAGEHI = 0, or 0 < RAGELO # RAGEHI

Other checks on card RRDATA
RRL # RR # RRU

If CA1, CA0, CO1 and CA0 are all +ve, then RR, RRL, RRU must equal (to 2 decimal places) the relative risk and CI as calculated according to the formula given in §3.4.3 of reference 1; if three are +ve and one zero, then the calculation will include the correction for zero cells described in that section, and DERIVE must be 7.

Consistency checks between cards RRDEF and RRADJ
ADSEX may be +ve only if RSEX=1

Consistency checks between cards RRADJ and RRDATA
CO1 and CO0 must be NA if and only if at least one field in card RRADJ is +ve.

Consistency checks between card RRDEF and study database
RSEX may be 2 only if SSEX is 1 or 2
RSEX may be 3 only if SSEX is 1 or 3
RSEX may be 1 only if SSEX is 1

RAGELO $SAGELO (except if RAGELO=RAGEHI=0)
If STYPE is 1, 3 (case-control or cross-sectional study) –
RAGEHI # SAGEHI (except if RAGELO=RAGEHI=0)

Must not have both RAGELO = SAGELO and RAGEHI = SAGEHI.

If STYPE is 2 (prospective study), similar conditions apply but with SAGEHF instead of SAGEHI.

RASTIM may be 1 only if LIFAST=1, and it may be 2 only if CURAST=1.

ONSET may be 1 only if STYPE=2 (prospective study).

Consistency checks between card RRADJ and study database
ADSEX may be 1 only if COSEX is 1.
ADAGE may be +ve only if COAGE is +ve.
ADRACE may be +ve only if CORACE is +ve.
ADOTHR may be +ve only if COMSMP, COCETS, COTETS, COHETS or COWETS is +ve.

ADOTHR+ADACSM+ADOETS # TOTCO-COSEX-COAGE-CORACE, except that ADOTHR may be 20 (meaning +ve but unknown) provided the sum is +ve. If less than (i.e. not equal) then a comment must be entered.

Consistency checks between card RRDATA and study database
CA1 + CA0 # NLAST if RASTIM=1, or CA1 + CA0 # NCAST if RASTIM=2.

If ONSET=0 (i.e. prevalence analysis) CA1+CA0+CO1+CO0 # NTOT.
If ONSET=1 (i.e. onset analysis) CO1+CO0 # NTOT. [This validation requirement was checked individually and waived for RRs where numbers of man-years at risk had been entered.]

Reference

1. Lee PN, Forey BA, Young KJ. *International evidence on passive smoking and childhood asthma induction (project IESAST). Part I: The databases; methods used to collect and analyse the data and scope of the information obtained.* Internal. 2004.