

# Blank Data Extraction Form and Quality Assessment Checklists (From the Original Report)

## ELIGIBILITY CRITERIA AND OTHER CHARACTERISTICS

UI	Author Year	Study Design*	Inclusion	Exclusion	Enrollment Years	Trial or Cohort Name	Funding Source	Extractor
		RCT RCT-post hoc** Other intervention study Cohort study Case-cohort study						

\*Leave appropriate choice of study design and delete all others

\*\*Post hoc analyses of an existing RCT for outcomes that were not planned in the original RCT

## POPULATION (BASELINE)\*\*

UI	Author Year	Study Design*	Location (e.g., City and Country, latitude)	N enrolled***	N analyzed	Mean (SD) Age, yr	Age Range / IQR	Male, %	Race / Ethnicity	Anthropometry Data (e.g., BMI, Weight, or %Body Fat ...etc.)	Health Status	Specific Nutrition Status Data (e.g., Malnourish, Low Vit D or Ca Intake ...etc.)

\*Please copy from above

\*\*Report baseline data for all subjects: preferred data for subjects actually analyzed than for subjects that enrolled in the study.

\*\*\*For RCT, N enrolled is the number of subjects randomized. For cohort study, N enrolled is the total number of subjects fulfilled study inclusion criteria. For case-cohort study, please report as detailed information as possible on subjects selection. For example, original cohort sample size, number of subjects provided exposure data (e.g. blood sample or dietary assessment), number of subjects had outcome data ...etc.

## Background diet\*

UI	Author Year	Exposure	Dietary Assessment Method**	Food Composition Database***	Internal Calibration (or Validity) of Dietary Assessment? (y/n) If Yes, Provide Data	Biomarker Assay****	Analytical Validity of Biomarker Data Reported? (y/n) If Yes, Provide Data	Time between Biomarker Sampling and Analysis	Season/Date when the biomarker samples were drawn	Background exposure data
		25(OH)D and/or 1,25(OH) <sub>2</sub> D								
		Dietary calcium intake								

\* Write "nd" if there was no data reported. Please do not leave blank

\*\*Please refer to common dietary assessment method table. If other method was used, please describe the detail. Otherwise, please simply use the brief name described in the table

\*\*\*USDA Nutrient Database, Minnesota Food and Nutrient Database (NDSR), Food product manufacturer, McCance and Widdowson's food table, Country-specific food tables, Other nutrient analysis (please specify)

\*\*\*\*ONLY biomarker of interest for calcium is calcium balance

**INTERVENTION(S), SKIP IF OBSERVATIONAL STUDY**

UI	Author Year	Intervention(s)	Source (e.g., brand name, foods, or formulation)	Vit D and/or Ca Total Daily Dose	Intervention Duration	Intervention Frequency (e.g. capsules were taken 2 times a day)
		<b>Co-intervention(s) *:</b>				
		<b>Compliance/Adherence:</b>				

Duplicate one row per intervention, including control intervention.

\*Report the non-vit D or Ca intervention(s) (e.g., other drug intervention, or background low-fat diet). We are interested in only independent effect of vitamin D and/or calcium. Therefore, describe how effects of co-intervention(s) were controlled for in the analyses or study design.

**LIST OF ALL OUTCOMES**

UI	Author Year	Primary / Secondary Outcome**	Outcome	Definition

Duplicate one row per outcome of interest. Only need to list outcomes that were included in the result section.

\*\*Must have been explicitly stated in the original paper. Otherwise, please enter "nd"

UI	Author Year	Comments

**Confounders: Please report all confounders controlled in the analyses reported in the following result section (adjusted results)**

UI	Author Year	Confounder Groups	Please List Name of Confounder (including matching factors)	Specific comments for confounders
		Other nutrients or dietary factors (e.g., certain food consumption), including supplement use and total energy intake Demographics (e.g., age, gender, race, education)? Anthropometrics (e.g., BMI, body weight, % body fat)? Medical conditions Medication Sunlight exposure and its proxy variables (e.g., seasonal variation of 25(OH)D, UV exposure, location) Smoking and other life styles variables (e.g., physical activity, occupation, alcohol consumption) Other	Yes/no* Yes/no*  Yes/no*	

\*Please choose "yes" if any one of the confounders in this group was controlled in the analysis

**FOLLOWING IS RESULT SECTION. PLEASE CHOOSE APPROPRIATE TYPE OF DATA COLLECTION TABLE FOR ALL OUTCOMES OF INTEREST**

**Main Analyses (For analyses that adjusted for confounders, choose the “best” model)**

**2 ARMS/GROUPS: DICHOTOMOUS OUTCOMES (e.g. OR, RR, %death)**

UI	Author Year	Outcome	Exposure/ Intervention	Mean Follow-up, mo	N Event	N Total	Outcome Metric (e.g. OR, RR, HR, %) and direction of comparison*	Unadjusted			Adjusted		
								Result	95% CI	P btw	Result	95% CI	P btw

\*Example: OR Ca/placebo

**2 ARMS/GROUPS: CONTINUOUS OUTCOMES (e.g. BMD, BP)**

UI	Author Year	Outcome	Unit	Exposure/ Intervention	Mean Follow-up, mo	No. Analyzed	Baseline	Baseline CI/SE/ SD*	Final or Delta**	Final or Delta CI/ SE/ SD*	Net difference	Net difference CI/SE/ SD*	P between

Baseline=baseline value; Final=final value; Delta=change value from baseline, which is Final-Baseline value; Net difference=differences in deltas

\*Enter outcome metric reported in the unadjusted or adjusted result section

\*\*Delta value is preferred than the Final value. Please report the direction for the change by using “+” or “-” sign: e.g. +2.8 or -2.8

**≥2 ARMS/GROUPS: DICHOTOMOUS OUTCOMES (e.g. OR, RR, %death)**

UI	Author Year	Outcome	Exposure Categories (e.g., Tertiles)/ Intervention Groups	Mean Vit D level/ dose	Mean Ca level/ dose	No. of Cases (Event)*	No. of Non-cases/ Total N**	Mean Follow-up, mo	Crude or Adjusted analysis?	Outcome Metric (e.g. OR, RR, HR, %)	Outcome effect size	CI/ SE/ SD**	P between groups***	P for trend****

Duplicate one row per exposure category or intervention group.

\*Number of subjects with outcome

\*\*Please choose one and delete the others

\*\*\*Specify the comparison. For example group 1 vs. 3 = -6; group 1 vs. 2 = -8

\*\*\*\*P value for testing the linear trend of the OR/RR across different categories or doses

≥2 ARMS/GROUPS: CONTINUOUS OUTCOMES (e.g. BMD, BP)

UI	Author Year	Outcome	Unit	Exposure Category/ Intervention Group	Crude or Adjusted analysis?	Mean Follow-up (months)	No. Analyzed	Baseline	Baseline CI/SE/ SD*	Final or Delta**	Final or Delta CI/ SE/ SD*	Net difference***	Net difference CI/SE/ SD*	P between groups***

Duplicate one row per exposure category or intervention group. Please write "nd" if there was no data reported. DO NOT LEAVE BLANK.

\*Please choose one and delete the others

\*\*Delta value is preferred than the Final value. Please report the direction for the change by using "+" or "-" sign: e.g. +2.8 or -2.8

\*\*\*Specify the comparison. For example group 1 vs. 3 = -6; group 1 vs. 2 = -8

MEAN DATA. THIS SHOULD ONLY APPLY TO CASE-COHORT STUDIES THAT COMPARE BASELINE VIT D / CA LEVELS BETWEEN CASES (WITH DISEASE) AND CONTROLS (WITHOUT DISEASE)

UI	Author Year	Outcome Group	Time between Baseline Exposure and Outcome Assessments	Crude or Adjusted analysis?	No. Analyzed	Mean 25(OH)D Level	Vit D level CI/SE/ SD*	Mean Ca intake or Ca balance	Ca CI/ SE/ SD*	P between groups
		Cases:								
		Control:								

Duplicate one table per outcome

OTHER RESULTS. ONLY USE THE FOLLOWING BOX WHEN THE TYPE OF RESULT DATA DO NOT FIT THE TABLES PROVIDED ABOVE

UI	Author Year	Outcome	Results

UI	Author Year	Comments for Results

### Subgroup Analyses

Please copy the appropriate table above for all subgroup analyses of interest.

**QUALITY of INTERVENTIONAL STUDIES**

UI	Author Year	Design*	Appropriate Randomization Technique (y/n/nd/NA)	Allocation Concealment (y/n/nd/NA)	Appropriate Washout Period (y/n/nd/NA)	Dropout Rate <20%	Blinded Outcome Assessment (y/n/nd)	Intention to Treat Analysis (y/n/nd)	Appropriate Statistical Analysis** (y/n)	Assessment for Confounding (y/n/nd/NA)	Clear Reporting with No Discrepancies (y/n)	OVERALL Grade
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Adverse Event(s): \*\*  
 Explanation for Overall Quality Grade (if not Grade A):

NA=not applicable

\*Please do not copy the 4 categories of study designs from above sections. Specify the exact study design: RCT – Parallel, RCT – Cross-over, RCT – Cluster, quasi-RCT, Non-randomized, but controlled trial, before-and-after trial, other interventional design (please explain in detail)

\*\*Please do not leave blank. Type nd if there was no data on adverse events.

**QUALITY of COHORT OR NESTED CASE-CONTROL STUDIES**

UI	Author Year	Population	Exposure (All)	Dietary assessment*	Biomarkers*	Comparator	Statistical Analysis	Outcome	Design
		a) Eligibility criteria clear? (y/n)	a) Exposure assessor blinded to outcome info? (y/n)	a) Method reported? (y/n)	a) One of the prespecified methods*** was used? (y/n)	a) Level of the exposure in comparative categories (e.g., quartiles) is given (ranges)? (y/n)	a) Adjusted or matched for ANY confounders (other than age and sex)?** (y/n)	a) Clear definition of outcome, including time of ascertainment? (y/n)	a) Prospective collection of data? (y/n)
		b) Sampling of population random or consecutive? (y/n)	b) Outcome assessor blinded to exposure measurement? (y/n)	b) Food composition database or suppl composition reported? (y/n)	Time from sample collection to sample analysis reported? (y/n)	applicable for categorical analyses only		b) Loss to follow-up <20%? (y/n)	b) Analysis was planned when cohort was formed? (y/n)
				c) Internal calibration of method perform (if FFQ)? (y/n/NA)			b) Justification of final adjusted model selection? (y/n)	c) Do the authors specify a primary outcome? (y/n)	c) Justification of sample size (includes sample size calculations)? (y/n)

OVERALL Grade (A/B/C):  
 Explanation for Overall Quality Grade (if not Grade A):

\*Check "NA" and skip all questions if study did not use dietary assessment or biomarkers

\*\*We will judge in the end if the set of confounders is adequate

\*\*\*Prespecified methods: HPLC, RIA kits, LC-MS/MS; EIA/Chemiluminescence