APPENDIX III – Data collection form

Data collection form

Name of reviewer :

Date :

Study ID (first author, year) :

Notes :

1. METHODS

1.1 Study design :

- ☐ Patient-randomized controlled trial
- ☐ Cluster-randomized controlled trial
- ☐ Quasi-randomized trial (units of allocation have been assigned prospectively to study groups using a quasi-random allocation method such as alternation, date of birth, or patient identifier)
- ☐ Controlled clinical trial (participants or other units have been *possibly* assigned prospectively using a process of random or quasi-random allocation)
- ☐ Controlled before-after study
- ☐ Interrupted time-series

1.2 Unit of allocation (i.e. who or what was allocated to study groups) :

- ☐ Patient
- ☐ Primary care physician
- ☐ Community pharmacist
- ☐ Primary care nurse
- ☐ Practice

☐ Pharmacy

☐ Institution (ex: hospital)

☐ Other : _____

☐ Unclear

1.3 Sequence generation method :

☐ Computer random number generator

☐ Random numbers table

☐ Coin tossing

☐ Shuffling cards or envelopes

☐ Throwing dice

☐ Sequence generated by some rule based on date (or day) of admission or on date (or day) of the screening clinic (nonrandom method)

☐ Sequence generated by some rule based on clinic or pharmacy record number (nonrandom method)

☐ Allocation by judgment of the clinician (nonrandom method)

☐ Allocation by preference of the participant (nonrandom method)

☐ Allocation by availability of the intervention (nonrandom method)

☐ Other : _____

☐ Not applicable

☐ Unclear

1.4 Allocation sequence concealment method :

☐ Central allocation (including telephone, web-based, and pharmacy-controlled randomization)

☐ Sequentially numbered, opaque, sealed envelopes

☐ Open random allocation schedule (e.g. list of random numbers) (unsealed procedure)

☐ Assignment envelopes used without appropriate safeguards (e.g. if envelopes were unsealed or non-opaque or not sequentially numbered) (unsealed procedure)

☐ Alternation or rotation (unsealed procedure)

☐ Date of birth, date of admission or date of screening clinic (unsealed procedure)

☐ Case record number (unsealed procedure)

☐ Other : _____

☐ Not applicable

☐ Unclear

2. PARTICIPANTS

2.1 Country where the study was conducted : _____

2.2 Study population :

☐ Patients **<u>at risk</u>** for osteoporosis and fractures
- women aged 65 years and older;
- men aged 70 years or older; and/or
- men/women over 50 with at least one major risk factor for osteoporosis (family history of osteoporosis, malabsorption syndrome, primary hyperparathyroidism, low BMD, hypogonadism, or early menopause)

☐ Patients **<u>at high risk</u>** for osteoporosis and fractures
- men/women receiving a daily dose of prednisone at >7.5 mg or equivalent for more than three months; and/or
- men/women with a previous fragility fracture (hip, wrist or spine)

☐ Combination of patients at risk and patients at high risk for osteoporosis and fractures

2.3 Study participants inclusion criteria (as reported in the paper) :

Patients	
Health professional (if applicable)	

2.4 Study participants exclusion criteria (as reported in the paper) :

Patients	
Health professional (if applicable)	

2.5 Gender of patients involved in the study :

- ☐ Women only
- ☐ Men and women
- ☐ Men only

3. INTERVENTIONS

If more than one intervention group, select the most intensive intervention (with the most components)

3.1 Please describe each component included in the intervention (as reported in the paper) :

Component	Description	Format (check all that apply)	Duration (if applicable)	Health professional/patient involved (check all that apply)
1		☐ Interpersonal/verbal ☐ Paper ☐ Audio/visual ☐ Computer/interactive ☐ Multiple media ☐ Other: _____ ☐ Unclear		☐ Primary care physicians ☐ Patients ☐ Primary care nurses ☐ Community pharmacists ☐ Medical specialists, please specify : _____ ☐ Other, please specify: _____
2		☐ Interpersonal/verbal ☐ Paper ☐ Audio/visual ☐ Computer/interactive ☐ Other : _____ ☐ Unclear		☐ Primary care physicians ☐ Patients ☐ Primary care nurses ☐ Community pharmacists

Component	Description	Format (check all that apply)	Duration (if applicable)	Health professional/patient involved (check all that apply)
				☐ Medical specialists, please specify : _____ ☐ Other, please specify: _____
3		☐ Interpersonal/verbal ☐ Paper ☐ Audio/visual ☐ Computer/interactive ☐ Other : _____ ☐ Unclear		☐ Primary care physicians ☐ Patients ☐ Primary care nurses ☐ Community pharmacists ☐ Medical specialists, please specify : _____ ☐ Other, please specify: _____
4		☐ Interpersonal/verbal ☐ Paper ☐ Audio/visual ☐ Computer/interactive ☐ Other : _____ ☐ Unclear		☐ Primary care physicians ☐ Patients ☐ Primary care nurses ☐ Community pharmacists ☐ Medical specialists, please specify : _____ (continued)

Component	Description	Format (check all that apply)	Duration (if applicable)	Health professional/patient involved (check all that apply)
				☐ Other, please specify: _____
5		☐ Interpersonal/verbal ☐ Paper ☐ Audio/visual ☐ Computer/interactive ☐ Other : _____ ☐ Unclear		☐ Primary care physicians ☐ Patients ☐ Primary care nurses ☐ Community pharmacists ☐ Medical specialists, please specify : _____ ☐ Other, please specify: _____
6		☐ Interpersonal/verbal ☐ Paper ☐ Audio/visual ☐ Computer/interactive ☐ Other : _____ ☐ Unclear		☐ Primary care physicians ☐ Patients ☐ Primary care nurses ☐ Community pharmacists ☐ Medical specialists, please specify : _____ ☐ Other, please specify: _____

Component	Description	Format (check all that apply)	Duration (if applicable)	Health professional/patient involved (check all that apply)
7		☐ Interpersonal/verbal ☐ Paper ☐ Audio/visual ☐ Computer/interactive ☐ Other : _____ ☐ Unclear		☐ Primary care physicians ☐ Patients ☐ Primary care nurses ☐ Community pharmacists ☐ Medical specialists, please specify : _____ ☐ Other, please specify: _____
8		☐ Interpersonal/verbal ☐ Paper ☐ Audio/visual ☐ Computer/interactive ☐ Other : _____ ☐ Unclear		☐ Primary care physicians ☐ Patients ☐ Primary care nurses ☐ Community pharmacists ☐ Medical specialists, please specify : _____ ☐ Other, please specify: _____

3.2 Please report elements of the Chronic Care Model involved in the intervention (check all that apply) :

☐ Self-management support (e.g. self-help or peer support groups, patient education classes, self-management tools such as flowcharts on which patients record their own laboratory results, self-management plans with self-improvement goals)

☐ Decision support (e.g. reminders based on evidence-based guidelines, continuous medical education (CME), academic detailing)

☐ Clinical information systems (e.g. creation of computerized registries to increase data accessibility, data sharing between health professionals, data sharing with patients)

☐ Health care organization (e.g. inter-professional collaboration, visit planning for continuous follow-up)

☐ Community resources and policies (e.g. efficient community programs, increase the collaboration between health professionals and community resources, improvement of use of non-medical resources)

3.3 Please describe the control group (check all that apply) :

☐ Usual care or no intervention

☐ Control intervention, please specify : _____

_____

_____

_____

☐ Other, please specify : _____

4. OUTCOMES

4.1 What is the maximal duration of follow-up after the intervention? _____

4.2 Please report the data collection method used for the following outcomes, if reported :

Outcome	Data collection method
BMD testing by DXA	☐ Telephone interview ☐ Self-administered mailed survey ☐ Face-to-face interview ☐ Administrative databases ☐ Electronic medical records ☐ Pharmacy records ☐ Other : _____ ☐ Not reported ☐ Unclear
Osteoporosis-treatment initiation[1]	☐ Telephone interview ☐ Self-administered mailed survey ☐ Face-to-face interview ☐ Administrative databases ☐ Electronic medical records ☐ Pharmacy records ☐ Other : _____ ☐ Not reported ☐ Unclear
Initiation of calcium/ vitamin-D supplements	☐ Telephone interview ☐ Self-administered mailed survey ☐ Face-to-face interview ☐ Administrative databases ☐ Electronic medical records ☐ Pharmacy records ☐ Other : _____ ☐ Not reported ☐ Unclear
BMD testing and/or osteoporosis-treatment initiation (composite endpoint)[2]	☐ Telephone interview ☐ Self-administered mailed survey ☐ Face-to-face interview ☐ Administrative databases ☐ Electronic medical records ☐ Pharmacy records ☐ Other : _____ ☐ Not reported ☐ Unclear

Fractures	☐ Telephone interview ☐ Self-administered mailed survey ☐ Face-to-face interview ☐ Administrative databases ☐ Electronic medical records ☐ Pharmacy records ☐ Other : _____ ☐ Not reported ☐ Unclear

[1] Includes bisphosphonates (alendronate, risedronate, etidronate, ibandronate, zoledronic acid), raloxifen, calcitonin, teriparatide, or hormone replacement therapy

[2] Excluding calcium/vitamin-D supplements

5. ANALYSES

5.1 Unit of analysis :

☐ Patient

☐ Primary care physician

☐ Community pharmacist

☐ Primary care nurse

☐ Practice

☐ Pharmacy

☐ Institution (ex: hospital, clinic)

☐ Other : _____

☐ Unclear

5.2 Were analyses done on an intent-to-treat basis?

☐ Yes

☐ No

☐ Unclear

5.3 If the study uses a cluster-randomized trial design, was data analysis free from unit-of-analysis error, i.e. were data analyzed using a statistical method taking the clustering into account (e.g. multilevel models, generalized estimating equations (GEEs), variance component analysis)?

☐ Yes

☐ No

☐ Unclear

☐ Not applicable

6. RESULTS

6.1 Please report the following numbers (N) of participants in each study group :

	Intervention group[1]	**Control group**
Total number of clusters that entered the study (if applicable)		
Total number of clusters randomized (if applicable)		
Total number of clusters lost to follow-up (if applicable)	N : Reasons :	N : Reasons :
Total number of clusters included in analyses (if applicable)		
Total number of patients who entered the study		
Total number of patients randomized (if applicable)		
Mean number of patients per cluster (if applicable)		

Total number of patients lost to follow-up	N : Reasons :	N : Reasons :
Total number of patients included in analyses		

[1] If more than one intervention group, select the most intensive intervention (with the most components)

6.2 Were patients/health professionals' baseline characteristics similar?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if baseline characteristics (or after randomization) of intervention and control patients/health professionals are reported and similar.
- Score "No" if there is no report of characteristics in text or tables or if there are differences between control and intervention patients/health professionals.
- Score "Unclear" if it is not clear in the paper.

6.3 Were incomplete outcome data adequately addressed?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if missing outcome measures were unlikely to bias the results (e.g. the proportion of missing data was similar in the intervention and control groups, reasons for dropouts not related to the intervention assigned).
- Score "No" if missing outcome data was likely to bias the results.
- Score "Unclear" if not specified in the paper (do not assume 100% follow-up unless stated explicitly).

6.4 Please report the number (N) and proportion (%) of patients in each study group with the following outcomes <u>after maximal follow-up</u> (check all that apply) :

Outcome	Follow-up duration	Intervention group[1]		Control group		p value
		N	%	N	%	
☐ BMD testing by DXA						
☐ Osteoporosis-treatment initiation[2]						
☐ Initiation of calcium/vitamin-D supplements						
☐ BMD testing and/ or osteoporosis-treatment initiation (composite endpoint)[3]						
☐ Fragility fractures						

[1] If more than one intervention group, select the most intensive intervention (with the most components)

[2] Includes bisphosphonates (alendronate, risedronate, etidronate, ibandronate, zoledronic acid), raloxifen, calcitonin, teriparatide, or hormone replacement therapy

[3] Excluding calcium/vitamin-D supplements

6.5 Please report effect sizes comparing the intervention group described in question 3.1 to the control group regarding the following outcomes, if applicable (check all that apply) :

OUTCOME: BMD TESTING BY DXA				
Effect size	**Point estimate**	**95% CI**	**p value**	**Covariates (control variables)**
☐ Crude RR				
☐ Adjusted RR				
☐ Crude OR				
☐ Adjusted OR				
☐ Other : _____				

OUTCOME: OSTEOPOROSIS-TREATMENT INITIATION[1]				
Effect size	**Point estimate**	**95% CI**	**p value**	**Covariates (control variables)**
☐ Crude RR				
☐ Adjusted RR				
☐ Crude OR				
☐ Adjusted OR				
☐ Other : _____				

[1] Includes bisphosphonates (alendronate, risedronate, etidronate, ibandronate, zoledronic acid), raloxifen, calcitonin, teriparatide, or hormone replacement therapy

OUTCOME: INITIATION OF CALCIUM/VITAMIN-D SUPPLEMENTS				
Effect size	**Point estimate**	**95% CI**	**p value**	**Covariates (control variables)**
☐ Crude RR				
☐ Adjusted RR				
☐ Crude OR				
☐ Adjusted OR				
☐ Other : _____				

OUTCOME: BMD TESTING AND/OR OSTEOPOROSIS-TREATMENT INITIATION (COMPOSITE ENDPOINT)[1]				
Effect size	**Point estimate**	**95% CI**	**p value**	**Covariates (control variables)**
☐ Crude RR				
☐ Adjusted RR				
☐ Crude OR				
☐ Adjusted OR				
☐ Other : _____				

[1] Excluding calcium/vitamin-D supplements

OUTCOME: FRAGILITY FRACTURES				
Effect size	**Point estimate**	**95% CI**	**p value**	**Covariates (control variables)**
☐ Crude RR				
☐ Adjusted RR				
☐ Crude OR				
☐ Adjusted OR				
☐ Other : _____				

6.6 <u>For studies using a cluster randomized trial design</u> : Please report the intra-class correlation coefficient (ICC) for the following outcomes, if reported in the paper :

Outcome	**Intra-class correlation coefficient (ICC)**
BMD testing by DXA	
Osteoporosis-treatment initiation[1]	
Initiation of calcium/vitamin-D supplements	
BMD testing and/ or osteoporosis-treatment initiation (composite endpoint)[2]	
Fragility fractures	

[1] Includes bisphosphonates (alendronate, risedronate, etidronate, ibandronate, zoledronic acid), raloxifen, calcitonin, teriparatide, or hormone replacement therapy

[2] Excluding calcium/vitamin-D supplements

7. RISK OF BIAS ASSESSMENT

If the present study is a randomized controlled trial, a controlled clinical trial or a quasi-randomized trial, please answer questions 7.1 to 7.7.

If the present study is a controlled before-after study, please answer questions 7.8 to 7.13.

If the present study is an interrupted time-series study, please answer questions 7.14 to 7.21.

Risk of bias assessment for randomized controlled trials (RCTs), controlled clinical trials (CCTs) and quasi-randomized trials :

7.1 Was the allocation sequence adequately generated?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if the investigators describe a random component in the sequence generation process (e.g. random number table, computer random number generator, coin tossing).
- Score "No" if the investigators describe a non-random component in the sequence generation process (e.g. sequence generated by date of birth, by some rule based on date or day of admission, or by some record number).
- Score "Unclear" if not specified in the paper.

7.2 Was the allocation adequately concealed?

☐ Yes

☐ No

☐ Unclear

Score "Yes" if

- the unit of allocation was by institution or practice and allocation was performed on all units at the start of the study and any random process is described explicitly (e.g. use of random number tables or coin flips);
  or
- the unit of allocation was by patient and there was some form of centralized randomization scheme, an on-site computer system or sealed opaque envelopes were used.

Score "No" if

- the authors report using alternation such as date of birth, day of the week, reference to case record number or any other such approach (as in CCTs);
  or
- the unit of allocation was by patient and the authors report using any allocation process that is entirely transparent before assignments such as open list of random numbers or assignments; or
- allocation was altered (by investigators, professionals or patients).

Score "Unclear" if

- the unit of allocation is not described explicitly;
  or
- the unit of allocation was by patient and the authors report using a "list", a "table", "envelopes" or "sealed envelopes" for allocation.

7.3 Was the follow-up of participants adequate?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if outcome measures were obtained for 80-100% of patients/health professionals randomized or of patients/health professionals who entered the trial (Do not assume 100% follow-up unless stated explicitly).
- Score "No" if outcome measures were obtained for less than 80% of patients/health professionals randomized or of patients/health professionals who entered the trial.
- Score "Unclear" if not specified in the paper.

7.4 Were outcomes assessed blindly?

☐ Yes

☐ No

☐ Unclear

Score "Yes" if

- the authors state explicitly that the outcome variables were assessed blindly and it is unlikely that the blinding could have been broken;
  or
- if there was no blinding but the outcome variables are objective (e.g. initiation of osteoporosis treatment as documented in administrative databases) or the assessor judge that the outcome measurement is not likely to be influenced by lack of blinding.

Score "No" if

- the outcomes were not assessed blindly;
  or
- the outcomes were assessed with incomplete blinding and the outcomes or outcome measurement are likely to be influenced by lack of blinding;
  or
- blinding was attempted but it is likely that the blinding could have been broken.

Score "Unclear" if not specified in the paper.

7.5 Were baseline outcome measurements similar?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if health professional performance or patient outcomes were measured prior to the intervention, and no important differences were present across study groups.
- Score "No" if there are differences at baseline in main outcome measures likely to undermine the post-intervention differences (e.g. differences between the groups before the intervention similar to those found post-intervention).
- Score "Unclear" if baseline measures are not reported, or if it's unclear whether baseline measures are substantially different across study groups.

7.6 Were outcome measures reliable?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if the outcome is obtained from some automated system (e.g. administrative databases) or from 2 or more raters with at least 90% agreement or kappa ≥0.8.
- Score "No" if agreement is less than 90% or kappa is less than 0.8.
- Score "Unclear" if reliability is not reported for outcome measures that are obtained by chart extraction or collected by an individual.

7.7 Was the study adequately protected against contamination?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if allocation was by institution, community or professional and it is unlikely that the control group received the intervention or if allocation was by patient and it is unlikely that the control group received the intervention.
- Score "No" if it is likely that the control group received the intervention (e.g. if patients rather than professionals were randomized).
- Score "Unclear" if professionals were allocated within a clinic or practice and it is possible that communication between intervention and control professionals could have occurred (e.g. physicians within practices were allocated to intervention or control group).

Risk of bias assessment for controlled before-after (CBA) studies

7.8 Were baseline outcome measurements similar?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if health professional performance or patient outcomes were measured prior to the intervention, and no important differences were present across study groups (e.g. where multiple pre-intervention measures describe similar trends in intervention and control groups).
- Score "No" if there are differences at baseline in main outcome measures likely to undermine the post-intervention differences (e.g. differences between the groups before the intervention similar to those found post-intervention).
- Score "Unclear" if baseline measures are not reported, or if it's unclear whether baseline measures are substantially different across study groups.

7.9 For studies using a second site as control: Were patients' and providers' characteristics similar?

☐ Yes

☐ No

☐ Unclear

☐ Not applicable

- Score "Yes" if characteristics of study and control patients and providers (if applicable) are reported and similar.

- Score "No" if there is no report of characteristics either in the text or a table or if baseline characteristics are reported and there are differences between study and control patients or providers (if applicable).
- Score "Unclear" if it is not clear in the paper.

7.10 Were outcomes assessed blindly?

☐ Yes

☐ No

☐ Unclear

Score "Yes" if
- the authors state explicitly that the outcome variables were assessed blindly and it is unlikely that the blinding could have been broken;
  or
- if there was no blinding but the outcome variables are objective (e.g. initiation of osteoporosis treatment as documented in administrative databases).

Score "No" if
- the outcomes were not assessed blindly;
  or
- the outcomes were assessed with incomplete blinding and the outcomes or outcome measurement are likely to be influenced by lack of blinding;
  or
- blinding was attempted but it is likely that the blinding could have been broken.

Score "Unclear" if not specified in the paper.

7.11 For studies using a second site as control: Was the study adequately protected against contamination?

☐ Yes

☐ No

☐ Unclear

☐ Not applicable

- Score "Yes" if allocation was by institution, community or professional and it is unlikely that the control group received the intervention.
- Score "No" if it is likely that the control group received the intervention.
- Score "Unclear" if professionals were allocated within a clinic or practice and it is possible that communication between intervention and control professionals could have occurred (e.g. physicians within practices were allocated to intervention or control group).

7.12 Were outcome measures reliable?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if the outcome is obtained from some automated system (e.g. administrative databases) or from 2 or more raters with at least 90% agreement or kappa ≥0.8.
- Score "No" if agreement is less than 90% or kappa is less than 0.8.
- Score "Unclear" if reliability is not reported for outcome measures that are obtained by chart extraction or collected by an individual.

7.13 Was the follow-up of patients/health professionals adequate?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if outcome measures were obtained for 80-100% of patients/health professionals who entered the study (Do not assume 100% follow-up unless stated explicitly).
- Score "No" if outcome measures were obtained for less than 80% of patients/health professionals who entered the study.
- Score "Unclear" if not specified in the paper.

Risk of bias assessment for interrupted time-series (ITSs)

7.14 Was the study adequately protected against secular changes?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if the intervention occurred independently of other changes over time.
- Score "No" if reported that intervention was not independent of other changes in time.
- Score "Unclear" if not specified.

7.15 Was data analyzed appropriately?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if ARIMA models were used or time series regression models were used to analyze the data and serial correlation was adjusted/tested for.
- Score "No" if it is clear that neither of the conditions above is met.
- Score "Unclear" if not specified.

7.16 Is the reason for the number of points pre and post intervention given?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if rationale for the number of points stated (e.g. monthly data for 12 months post-intervention was used because the anticipated effect was expected to decay) or sample size calculation performed.
- Score "No" if it is clear that neither of the conditions above is met.
- Score "Unclear" if not specified.

7.17 Was the shape of the intervention effect specified?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if a rational explanation for the shape of intervention effect was given by the author(s).
- Score "No" if it is clear that the condition above is not met.
- Score "Unclear" if not specified.

7.18 Was the study adequately protected against detection bias?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if reported that intervention itself was unlikely to affect data collection (for example, sources and methods of data collection were the same before and after the intervention).
- Score "No" if the intervention itself was likely to affect data collection (for example, any change in source or method of data collection reported).
- Score "Unclear" if not reported.

7.19 Were outcomes assessed blindly?

☐ Yes

☐ No

☐ Unclear

Score "Yes" if
- the authors state explicitly that the outcome variables were assessed blindly and it is unlikely that the blinding could have been broken;
  or
- if there was no blinding but the outcome variables are objective (e.g. initiation of osteoporosis treatment as documented in administrative databases).

Score "No" if
- the outcomes were not assessed blindly;
  or
- the outcomes were assessed with incomplete blinding and the outcomes or outcome measurement are likely to be influenced by lack of blinding;
  or
- blinding was attempted but it is likely that the blinding could have been broken.

Score "Unclear" if not specified in the paper.

7.20 Was the data set complete?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if data set covers 80-100% of total number of participants in the study.
- Score "No" if data set covers less than 80% of the total number of participants in the study.
- Score "Unclear" if not specified.

7.21 Were primary outcome measures reliable?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if the outcome is obtained from some automated system (e.g. administrative databases) or from 2 or more raters with at least 90% agreement or kappa ≥0.8.
- Score "No" if agreement is less than 90% or kappa is less than 0.8.
- Score "Unclear" if reliability is not reported for outcome measures that are obtained by chart extraction or collected by an individual.

8. MISCELLANEOUS

8.1 Was the study free from other risks of bias?

☐ Yes

☐ No

☐ Unclear

- Score "Yes" if there is no evidence of other risk of biases.
- Score "No" if there is evidence of other risk of biases (e.g. study stopped early due to some data-dependent process, individuals recruited after the clusters have been randomized if randomized by clusters).

8.2 Funding source : _____